

**Q3 2010**

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# **INDONESIA**

## **PHARMACEUTICALS & HEALTHCARE REPORT**

INCLUDES 10-YEAR FORECASTS TO 2019





# INDONESIA PHARMACEUTICALS & HEALTHCARE REPORT Q3 2010

Including 5-year and 10-year industry forecasts by BMI

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## Part of BMI's Industry Survey & Forecasts Series

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## Executive Summary

In the **BMI** Business Environment Rating matrix for Q310, we see Indonesia continue to occupy 12<sup>th</sup> position of the 16 regional markets surveyed in the Asia Pacific region. The country's pharmaceutical rating has risen to 47.2, marking a marginal increment over the previous quarter. However, it is still lower than the average for the region. The main drawbacks to investment in the country include corruption, low per-capita spending on pharmaceuticals and a small proportion of the elderly in the country. On the other hand, factors such as annual growth of its pharmaceutical market, coupled with rising population numbers and a relatively solid political and economic base are expected to encourage multinationals to invest in the country despite a risky operating environment. We therefore envisage that sales of pharmaceutical products will increase over the next 10 years, with sales of prescription drugs and over-the-counter (OTC) medicines expected to grow from US\$2.92bn to US\$10.13bn, thus representing compound annual growth rates (CAGRs) in local currency terms of 10.89% and 10.35% for 2009-14 and 2014-19 respectively.

The Ministry of Finance has introduced new guidelines for all taxpayers on the deductibility of promotional expenses. The new directive also revokes an existing law which placed a cap on the deductibility of promotional expenses for taxpayers in the tobacco and pharmaceutical industries. Given that it is also applied with retrospectively from 1 January 2009, it impacts all tax returns filed by the 30 April deadline.

Meanwhile, the Ministry of Health announced that it was preparing a new decree requiring doctors at state-run medical facilities to prescribe generic drugs wherever possible as a means of controlling rising healthcare costs. The new policy would modify and more strictly enforce a similar decree enacted in 1989, which has never been fully implemented.

In its Special 301 Submission for 2010, PhRMA and its member companies operating in Indonesia have voiced their concern about the continued market access barriers that stem from regulations promulgated with little notice and no input from the research-based pharmaceutical industry. Key areas of concern include weak counterfeit enforcement, the Ministerial Decree 1010, Halal labelling regulations, Indonesia's Health Law, as well as non-conformance to international best practices in the pharmaceutical registration process. For these reasons, PhRMA has requested that Indonesia be placed on the Priority Watch List for the 2010 Special 301 Report.

Elsewhere, the Indonesian government announced that it is to implement its long-awaited National Social Security System (*Sistem Jaminan Sosial Nasional*; SJSN) Law of 2004 later this year. The policy, which forms part of President Susilo Bambang Yudhoyono's five-year plan, would ensure every citizen is insured through social or commercial health insurance. The SJSN aims to include all Indonesians in a system of pre-paid contributions and assistance spanning pensions, work injury, health insurance, old-age savings and death benefits.

# SWOT Analysis

## Indonesia Pharmaceutical And Healthcare Industry SWOT

<b>Strengths</b>	<ul style="list-style-type: none"> <li>▪ Significant market growth potential, with a fast-growing population.</li> <li>▪ Well-established local industry, with domestic players especially prominent in manufacturing.</li> <li>▪ Sizeable and strong generic drug market, largely owing to the low-income population.</li> <li>▪ Introduction of Good Manufacturing Practice (GMP) standards.</li> </ul>
<b>Weaknesses</b>	<ul style="list-style-type: none"> <li>▪ The market is among the least developed in Asia.</li> <li>▪ No private insurance and no pharmaceutical reimbursement.</li> <li>▪ Lack of formal price controls leading to delays or rejections of marketing applications if the proposed price is deemed too high.</li> <li>▪ Low purchasing power of large section of the population.</li> <li>▪ Regulatory system biased in favour of local drug producers.</li> <li>▪ Reliance on imports, in value terms, placing considerable pressure on already strained government healthcare finances.</li> <li>▪ Counterfeit drugs account for as much as 20% of the market, posing a major barrier to foreign investment.</li> <li>▪ Pharmaceutical sales through illegal channels.</li> <li>▪ Reliance on imported active pharmaceutical ingredients (APIs), which makes the industry sensitive to currency fluctuations.</li> </ul>
<b>Opportunities</b>	<ul style="list-style-type: none"> <li>▪ Demand for low-cost drugs to increase with the continuing expansion of the healthcare sector and rising cost awareness.</li> <li>▪ Trade liberalisation within the Association of South East Asian Nations (ASEAN) regional group to potentially speed up growth, as could government subsidies of healthcare costs.</li> <li>▪ Exports likely to rise as more producers meet GMP standards.</li> <li>▪ The proposed privatisation of the local manufacturing industry holds considerable benefits for the industry from private control and funding.</li> <li>▪ Rising attractiveness of Indonesia as a clinical trials base.</li> <li>▪ Government encouragement of exports.</li> <li>▪ Despite some problems with the programme, the government is planning to consolidate the local industry in order to reduce costs.</li> </ul>
<b>Threats</b>	<ul style="list-style-type: none"> <li>▪ Potential removal of the pharmaceutical industry from the 'negative investment' list.</li> <li>▪ Poor intellectual property (IP) protection leading to reduced foreign investment (FDI).</li> <li>▪ Poor efficacy of counterfeit drugs leading to a distrust of pharmaceuticals.</li> <li>▪ Inadequate healthcare coverage and lack of disease monitoring leading to epidemics.</li> <li>▪ Recently introduced regulation stipulating that all foreign companies must have local manufacturing facilities.</li> <li>▪ Escalating raw material cost and taxation of imports resulting in pharmaceutical products becoming prohibitively expensive.</li> <li>▪ Widespread corruption continuing to deter foreign investment.</li> <li>▪ Reduction of tariffs on drugs under ASEAN harmonisation programme posing threat to local industry</li> </ul>

## Indonesia Political SWOT

<b>Strengths</b>	<ul style="list-style-type: none"><li>▪ Indonesia managed a successful transition to democracy in 2004. In addition, the 2009 parliamentary and presidential elections passed by peacefully, signalling the consolidation of the democratic process.</li><li>▪ The military's role in politics has gradually been reduced. The prospects of a military coup – which seemed a real possibility in the late 1990s and early 2000s – have diminished substantially.</li></ul>
<b>Weaknesses</b>	<ul style="list-style-type: none"><li>▪ Indonesia's domestic political scene is characterised by a proliferation of minority parties, and formal and informal coalitions are necessary to govern and legislate. Moreover, the efficiency of state institutions is encumbered by bureaucracy and corruption.</li><li>▪ Indonesia's cultural and ethnic diversity saw the archipelago wracked by separatist rebellion and ethnic violence in the late 1990s and early 2000s, which took great efforts to bring to heel. In the event of a new economic crisis, calls for regional secession could re-emerge.</li></ul>
<b>Opportunities</b>	<ul style="list-style-type: none"><li>▪ President Susilo Bambang Yudhoyono's Democratic Party had a strong showing in the 2009 parliamentary elections. Coupled with a strong mandate following his re-election in the same year, the implementation of policies in the legislature should potentially become less problematic.</li><li>▪ Indonesia's status as the world's most populous Muslim country leaves it well positioned to speak out on global Islamic issues, and act as a bridge between the Middle East and the Asia-Pacific region.</li></ul>
<b>Threats</b>	<ul style="list-style-type: none"><li>▪ Regional militant group Jemaah Islamiah (JI) poses a lingering threat to security in Indonesia. JI is blamed for a series of attacks, including the Bali bombings of October 2002 and other such incidents, including the Jakarta bombings of July 2009.</li><li>▪ The fact that Indonesia subsidises basic goods means that when the government raises prices, there is a risk of public unrest, or at least a political backlash.</li></ul>



#### Indonesia Economic SWOT

<b>Strengths</b>	<ul style="list-style-type: none"><li>▪ Indonesia's strategic location between the Indian and Pacific Oceans and its adjacency to major East-West trade routes make it an important economy in the region.</li><li>▪ Indonesia has a low cost and large supply of available labour resources.</li></ul>
<b>Weaknesses</b>	<ul style="list-style-type: none"><li>▪ Indonesia's economy is not growing fast enough to reduce joblessness. Although unemployment has been decreasing, the unemployment rate is still relatively high, at 8.1% in February 2009. Many are forced to work in the informal sector.</li><li>▪ Indonesia's physical infrastructure is considered substandard. The archipelagic nature of the country makes it difficult to weave national infrastructure together.</li></ul>
<b>Opportunities</b>	<ul style="list-style-type: none"><li>▪ Indonesia could attract much-needed foreign investment by strengthening its business environment, particularly through reform of its unreliable legal system.</li><li>▪ Indonesia stands to benefit from the rise of Islamic financing, having adopted new legislation in early 2008 designed to tap into this rapidly expanding sphere.</li></ul>
<b>Threats</b>	<ul style="list-style-type: none"><li>▪ Production at Indonesia's ageing oil fields has been in decline since the mid-1990s. Thus, the country has become a net importer of crude oil in recent years, adding downward pressure on its current account position.</li><li>▪ Indonesia is perceived as one of Asia's riskier destinations. This leaves the economy vulnerable to sudden capital outflows at times of risk aversion, which can lead to sharp swings in the currency.</li></ul>

## Indonesia Business Environment SWOT

<b>Strengths</b>	<ul style="list-style-type: none"> <li>Indonesia is South East Asia's largest economy with a nominal GDP of US\$500bn, and is the world's fourth-most populous country with almost 240mn people. It thus offers investors a vast home market in which to do business.</li> <li>Indonesia is also a founding member of the Association of South East Asian Nations (ASEAN). As a member of ASEAN's Free Trade Area (AFTA), Indonesia is committed to lowering tariff and non-tariff barriers to trade.</li> </ul>
<b>Weaknesses</b>	<ul style="list-style-type: none"> <li>Corruption remains a major problem. Indonesia ranked 111<sup>th</sup> out of 180 countries surveyed in Transparency International's 2009 Corruption Perceptions Index, where a low ranking denotes a higher degree of corruption.</li> <li>Indonesia's excessive bureaucracy makes it a difficult place to do business. Among Asian economies, Indonesia has the longest period to start a business. Labour laws are also considered excessive.</li> </ul>
<b>Opportunities</b>	<ul style="list-style-type: none"> <li>The Yudhoyono administration has gradually been reforming the business environment, particularly by strengthening the legal system and fighting corruption. If sustained, this would boost investor interest in Indonesia.</li> <li>Indonesia has been amending its debt and banking regulations in 2008, with the aim of attracting Islamic financial activities.</li> </ul>
<b>Threats</b>	<ul style="list-style-type: none"> <li>Recent high-level business disputes between the government and foreign investors demonstrate that even after investments become up-and-running, there is still scope for legal problems or obstacles posed by legal wrangling.</li> <li>Security threats are a concern for investors. Despite several of its top leaders having been arrested in recent years, Jemaah Islamiah, the radical Islamist militant group blamed for the Bali bombings, remains active. There is also a low-level threat from separatist rebels or from intercommunal tensions.</li> </ul>

## Pharmaceutical Business Environment Rating

**Table: Asia Pacific – Regional Pharmaceutical Business Environment Rankings For Q310**

	Limits of potential returns			Risks to realisation of returns			Pharma rating	Regional ranking
	Pharmaceutical market	Country structure	Limits	Market risks	Country risk	Risks		
South Korea	67	60	65	70	69	70	66.9	1
Australia	57	73	61	72	82	76	66.9	2
Japan	60	70	63	73	72	73	66.7	3
China	67	43	61	67	55	62	61.3	4
Singapore	37	67	44	80	88	83	59.8	5
Taiwan	50	53	51	70	64	68	57.6	6
Hong Kong	40	70	48	67	78	71	57.0	7
India	60	40	55	60	53	57	55.9	8
Malaysia	40	57	44	70	68	69	54.2	9
Thailand	60	43	56	37	61	47	52.1	10
Philippines	50	57	52	43	48	45	49.1	11
<b>Indonesia</b>	<b>53</b>	<b>47</b>	<b>52</b>	<b>40</b>	<b>41</b>	<b>40</b>	<b>47.2</b>	<b>12</b>
Vietnam	47	40	45	40	49	43	44.4	13
Bangladesh	43	30	40	43	35	40	40.0	14
Pakistan	27	47	32	33	44	37	34.0	15
Cambodia	33	20	30	30	37	33	31.2	16
<b>Regional Average</b>	<b>49</b>	<b>51</b>	<b>50</b>	<b>56</b>	<b>59</b>	<b>57</b>	<b>52.8</b>	

Scores out of 100, with 100 highest. Source: BMI

In the **BMI** Business Environment Rating matrix for Q310, we see Indonesia continue to occupy 12<sup>th</sup> place, out of the 16 regional markets surveyed in the Asia Pacific region. The country's pharmaceutical rating has risen to 47.2, marking a slight increase over the previous quarter. However, it is still lower than the average for the region. The main drawbacks to investment in Indonesia include corruption, low per-capita spending on pharmaceuticals and a small proportion of the elderly in the country. On the other hand, factors such as annual growth of its pharmaceutical market, coupled with rising population numbers and a relatively solid political and economic base are expected to encourage multinationals to invest in the country despite a risky operating environment. The component parts of Indonesia's Business Environment rating are:

## Limits of Potential Returns

Pharmaceutical Market and Country Structure scores are weighted and combined to form Limits of Potential Returns. Indonesia scores 52 out of 100.

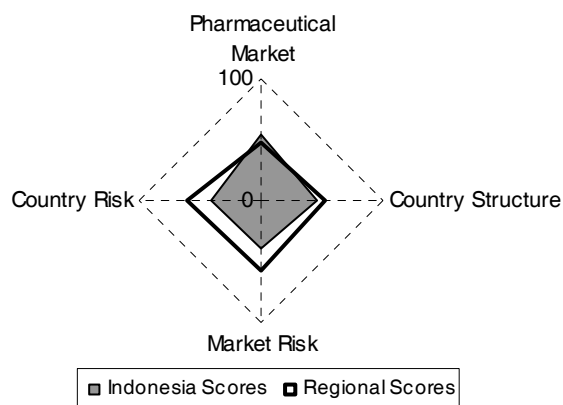
### Pharmaceutical Market

Indonesia's pharmaceutical market received a score of 53, which is considerably above the average for the 16 markets in the Asia Pacific region.

Indonesia is a lower-middle-income country, where a significant proportion of the population does not have access to adequate healthcare and, as a result,

pharmaceuticals remain prohibitively expensive for many. Nevertheless, the demand for drugs will rise over the forecast period, due to an increased need for modern medicines, population growth and healthcare service improvements, as well as developing economic conditions. However, a serious weakness in the market remains the lack of up-stream manufacturing capacity. This leaves pharmaceutical companies reliant on imports of APIs, and highly sensitive to fluctuations in the exchange rate.

### Business Environment Ratings By Sub-Sector Score, Q310



Scores out of 100. Source: BMI

### Country Structure

Indonesia's score for this indicator is 47 out of the possible 100, on a par with Pakistan and considerably below the regional average of 51. The score reflects a small pensionable population in comparison to its Asian peers, as well as a vast number of rural dwellers. On a positive note, Indonesia's population is fast growing, which should uphold the development of its pharmaceutical market. Domestic producers are primarily focused on the production of basic drugs such as generics and over-the-counter (OTC) products. The generic medicine market is expected to grow significantly in the coming years, as consumption of these products has been rising steadily due to government promotion of the sector.

## Risks to Realisation of Returns

Market and Country Risks are weighted and combined to form the score for Risks to Realisation of Potential Returns. Indonesia's score of 40 falls considerably below the regional average of 57. Indonesia is, therefore, generally not viewed as a favourable destination for investment and involvement by foreign pharmaceutical manufacturers. Nevertheless, multinationals already operating manufacturing facilities in the country, including **Sanofi-Aventis**, **Bayer**, **Bristol Myers-Squibb (BMS)** and **Schering-Plough** will continue to benefit from low production costs.

### **Market Risks**

Indonesia again scored just 40 for Market Risks, which is among the lowest scores in the table. The figure reflects intellectual property rights (IPR) deficiencies from the point of view of foreign research-based companies. Specific concerns include an increase in counterfeiting related to parallel imports, the absence of enforcement of current IP provisions and the lack of data exclusivity. In addition, domestic procedures are heavily weighted in favour of local companies. Meanwhile, a decree by the national regulatory authority BPOM in November 2008 has imposed excessive penalties on pharmaceutical companies that do not own local manufacturing facilities.

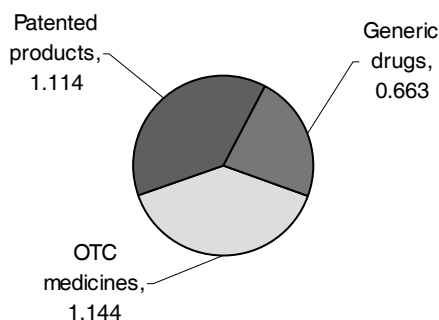
### **Country Risk**

Indonesia received a score of 41 for Country Risk. On the upside, the country is viewed as having relatively solid continuity of policy and an economic base. On the downside, Indonesia scored poorly in terms of corruption, red tape and legal framework, with the three conspiring to pose considerable risks to foreign investors in the country. In fact, despite an ongoing anti-corruption drive, Indonesia remains a highly corrupt country. The head of Indonesia's Corruption Eradication Commission (KPK), Antasari Azhar, was actually arrested in May 2009 over his alleged involvement in the drive-by killing of businessman Nasrudin Zulkarnaen. Antasari played critical roles while heading the KPK and was an integral part of President Susilo Bambang Yudhoyono's push to clamp down on rampant corruption. Indeed, Antasari was credited with several high-profile arrests since taking office in December 2007. Aside from corruption, potential security risks also undermine the business environment. Although Indonesia is lowering its corporate tax rates from 30% to 25% by 2010 in order to attract FDI, the effect of this will be limited without improvement in the other spheres of business.

## Market Summary – Indonesia

The value of the Indonesian pharmaceutical market was calculated to be IDR26,889bn (US\$2.79bn) in 2009, according to composite figures from the Association of the European Self-Medication Industry (AESGP), IMS Health Asia, the Indonesian Association of Pharmaceutical Companies (GP Farmasi) and AC Nielsen. Despite its sizeable and fast-growing population, Indonesia is unlikely to achieve its full pharmaceutical growth potential due to economic and political difficulties.

**Pharmaceutical Market By Sub-Sector (US\$bn)**  
2009



The low purchasing power of the population means that the marketplace for medicines is restricted to a relatively

*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health, GP Farmasi, AC Nielsen, local companies, BMI*

small consumer base. This situation is compounded by the fact that many local generics – a low-cost product in most countries – are often prohibitively expensive. The high price of these drugs partly results from the domestic industry's reliance on imported inputs, making final prices sensitive to currency movements. On a positive note, exports – driven by GMP certification gained by local manufacturers – will continue to increase steadily, mirroring the trend over recent years.

As leading domestic manufacturers gradually gain strength, the sector's prospects look positive. Several firms including **PT Kalbe Farma** have been exporting significant amounts of more basic pharmaceutical products, such as analgesics, for some years. Nigeria represents the leading destination and the Middle East is also a growing market for exports, with the advantage of Indonesia's Muslim identity proving a key to increasing trade links. Of approximately 200 drug companies operating in the market, 162 are local while 38 are foreign-owned, according to GP Farmasi. Local drugmakers account for approximately 70% of the market, with foreign firms taking the remainder. In 2008, local drugmakers recorded around 15% profit growth, compared to 10% for overseas firms.

The two largest state-held drug companies in Indonesia are **Kimia Farma**, which is 90.03%-owned by the state, and **Indofarma**, in which the government has an 81.0% stake. The government has plans to consolidate the state-owned production *en route* to privatisation, which should provide some relief from increased competition. A number of multinationals have a direct manufacturing presence in Indonesia, including **Sanofi-Aventis**, **Bayer**, **Bristol Myers Squibb** (BMS) and **Schering-Plough**. Others import

their products through local distributors. However, counterfeit drugs, made possible by the lack of effective product patent and data protection, are an enduring problem and account for up to 20% of all pharmaceutical sales.

## Regulatory Regime

The main regulatory authority in Indonesia is the government-controlled National Agency of Drug and Food Control/Badan Pengawas Obat dan Makanan (NADFC/BPOM). The agency was created in 2001 as a part of a major restructuring of the regulatory system. It has broader authority than its predecessor, and reports directly to the president. Its main objectives are to protect the population from unsafe therapeutic products and traditional medicines. BPOM claims to prioritise accelerating the drug approval process and improving transparency.

Registering drugs remains a lengthy and complicated process in Indonesia, with delays estimated to range from one to three years. Industry observers are still calling for greater transparency – particularly regarding the fees charged for submitting an application, as well as the guidelines for registering a new chemical entity (NCE). Presently, there are around 17,000 registered drugs on the Indonesian market.

While significant deficiencies still exist, an important step towards the harmonisation of pharmaceutical regulations took place in July 2009 when the drug regulatory agencies of ASEAN member nations agreed to harmonize standards and regulations of pharmaceutical products at the 16<sup>th</sup> Meeting of the ASEAN Consultative Committee for Standards and Quality-Pharmaceutical Product Working Group (ACCSQ PPWG), held in May this year. The three principle aims of the initiative are to create a transparent regulatory process; standardise regulation requirements; and remove the need for duplicate studies to meet various regulation requirements. Manufacturers would be required to follow the ASEAN Common Technical Documents (ACTD) in order to be certified as compliant. It is hoped such a move would enable pharmaceutical companies to spend more time and allocate more resources towards the research and development of new drugs.

The proposed harmonisation will extend to all components of the pharmaceutical manufacturing process, from testing, to raw materials, to production. The ACCSQ hopes that this synchronization of standards will not only lower the cost, but also increase the quality and availability of medicines to countries within the ASEAN regional trade bloc. At the same time, the group aims to fortify rules on importing drugs, so as to maintain the quality of medicines brought into any one of the Southeast Asian countries.

Medicines are classified into the following categories: narcotics (category O), prescription medicines (category G), OTC medicine with warning labels (category W), and general OTC medicines (category F). Traditional medicines are classed as standardised herbal medicines, *Jamu* (traditional Indonesian drug) and phytopharmaceuticals, all of which can be sold as OTCs.

Narcotics and prescription medicines can be dispensed only in retail pharmacies, upon presentation of a prescription. Other outlets, such as drug stores, sell OTC medicines with warning labels and general OTC medicines, while the latter can also be obtained through supermarkets and general stores. However, lax



legislation enforcement means that peddlers are also responsible for a substantial proportion of total pharmaceutical sales. Both prescription and OTCs can be obtained through teleshopping.

The NADFC also controls drug advertising. Drugs classed as G cannot be advertised to the public, while W drugs can be advertised to consumers, provided they have warning messages on packages. There is no restriction on the advertising of category F products. All advertising material must be approved by the NADFC.

While direct-to-consumer (DTC) pharmaceutical advertising is only permitted in the US and New Zealand, other countries have determined that this practice encourages ‘disease-mongering’ and the over-consumption of expensive, branded medicines. Therefore as an alternate means to maximising sales in non-DTC markets, drug manufacturers promote their products to healthcare professionals through the provision of ‘incentives’ – such as gifts, trips or cash bonuses – to doctors for prescribing certain medicines and meeting targets. This however, is often seen as unethical.

In October 2009, the Ministry of Finance introduced new guidelines (citation PMK.02/PMK.03/2010), for all taxpayers on the deductibility of promotional expenses. The new directive also revokes an existing law which placed a cap on the deductibility of promotional expenses for taxpayers in the tobacco and pharmaceutical industries. The directive, which applies equally to all taxpayers, introduces an extra administrative requirement for taxpayers who seek to deduct promotional expenses. Given that it is also applied retrospectively as of 1 January 2009, it impacts all tax returns filed by the 30 April deadline.

The new regulation considers promotional expenses to be those which are ‘spent in order to introduce customers to a product, suggest the usage of a product to customers, and/or increase/maintain sales’. More specifically, the regulation identifies promotional expenses that can be deducted as being advertising expenses, product exhibition expenses, new product introduction expenses and/or sponsorship expenses that are related to the promotion of products.

Under the new legislation, the normal rules for deductibility apply. In order for an expense to be deductible, such costs must still be incurred in relation to earning income which is subject to tax. However, given that the focus of the deductible promotional expenditure appears to be ‘product’ oriented rather than just ‘brand’ oriented, speculation remains as to whether general brand building promotional expenses will be able to satisfy the deductibility requirements of the new regulation.

For taxpayers in the pharmaceutical and tobacco industries, the new regulation also revokes an earlier directive (citation PMK.104/PMK.03/2009), which placed a cap on the ability to deduct promotional expenses. It is thought that for this category of taxpayer, the new regulation will be a welcome development, particularly given the levels of promotional expenditure that occur within each sector. For example, a typical multinational pharmaceutical manufacturer spends 30% of its global turnover on ‘selling, general and administrative’ activities. Because of this, it is expected that foreign firms will be

affected most by the new rules. In response to the new measures, Indonesia's International Pharmaceutical Manufacturer Group (IPMG) has voiced its support of the government's efforts to promote ethical marketing behaviour among companies operating in the healthcare sector.

The rules that govern the new regulation require a nominative list to be attached to the annual corporate income tax return (CITR), setting out substantial amounts of data regarding the recipient of the payment, including the Tax ID and withholding tax slip number (if any). For most taxpayers, this list of requirements would represent a greater amount of data than is currently being collected in relation to promotional expenses. Therefore in order to be entitled to the deduction, all of the required information must be included on the nominative list attached to the CITR.

More recently, in January 2010, Indonesia's Ministry of Health announced that it was preparing a new decree requiring doctors at state-run medical facilities to prescribe generic drugs wherever possible as a means of controlling rising healthcare costs. According to the Minister of Health, Endang Rahayu Sedyaningsih, the new policy would modify and more strictly enforce a similar decree enacted in 1989, which in fact, has never been fully implemented. While there has been speculation that the government may eventually attempt to extend the mandate beyond state-run clinics and hospitals, the likelihood and timing of such a measure are at present, uncertain.

Changes to the current system are seen as an attempt by the government to address local criticism of both rising healthcare costs and the alleged widespread irregular practices adopted in the promotion of drugs. While I-health insurance schemes currently cover only civil servants and the very poor, medical facilities tend to be heavily reliant on profit margins derived from drugs. This, together with improper promotional activities – which can include gifts, travel, bonuses and other inducements – are seen by the government as contributory factors that perpetuate the use of more expensive drugs. While several codes and agreements on promotional ethics already remain in place, both industry and doctor groups have strongly denied any impropriety in their activities. Therefore, the new generics decree, if passed, would still allow the use of branded drugs in instances where suitable generic alternatives were unavailable.

Indonesia's domestic industry is dominated by several large manufacturers set up as fully state-owned entities, which produce a broad range of common generics. However, such products have also come under pricing pressures in the past few years through other mandates, some of which have stipulated price reductions of up to 30% for certain drugs. Indonesia's overall healthcare budget is expected to rise by 20% to reach approximately IDR20bn (US\$2.1bn) this year, in part to meet national health targets.

## Intellectual Property Issues

The government and the international drug industry continue to clash over the issue of patent and IP protection, which is considered inadequate in both law and practice. A notable example concerns patchy implementation of the provisions of the World Trade Organization (WTO)'s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which was originally due to be fully enforced by 2000. Similarly, a copyright law introduced in 2003 has so far been widely reported as ineffective. Sluggish progress is blamed on the government's desire to protect the local industry as much as heavy-handed and inefficient procedures. The government is considering using the compulsory licensing loophole in the TRIPS agreement when there is a public health interest to produce three patented antiretroviral (ARV) drugs; these are US-based **Gilead**'s *Virea*, (tenofovir), BMS' *Videx* (didanosine) and **Abbott Laboratories**' *Kaletra/Aluvia* (lopinavir + ritonavir).

Although in 2005 the US trade association Pharmaceutical Research and Manufacturers of America (PhRMA) opted not to lobby for Indonesia's inclusion in the USTR's list of countries where IP rights are threatened, the country was added to the list in 2006. In the 2007 report, Indonesia remained on the Watch List, having been lowered from the Priority Watch List at the conclusion of an Out-of-Cycle Review in November 2006. However, in 2009, the country was again placed on the 'Priority Watch List'.

In its Special 301 Submission for 2010, PhRMA and its member companies operating in Indonesia have voiced their concern about the continued market access barriers that stem from regulations promulgated with little notice and no input from the research-based pharmaceutical industry. Key areas of concern include weak counterfeit enforcement, the Ministerial Decree 1010, Halal labelling regulations, Indonesia's Health Law, as well as non-conformance to international best practices in the pharmaceutical registration process. For these reasons, PhRMA has requested that Indonesia be placed on the Priority Watch List for the 2010 Special 301 Report.

Despite the establishment of a National Anti-counterfeiting Task Force and recent efforts by the Indonesian government to stop piracy activities within the pharmaceutical sector, counterfeit medicines continue to be a significant problem in Indonesia. While PhRMA welcomes Indonesia's recent attempts to address the problem of counterfeit medicines (for example, the government recently hosted a conference on combating counterfeit medicines in association with ASEAN, China, the WHO and Interpol), PhRMA believes there is an urgent need to expand national enforcement efforts for counterfeit pharmaceutical products. However, **BMI** warns that this will be difficult due to large levels of corruption in the country, with the head of the Corruption Eradication Commission recently arrested on suspicion of murder.

Meanwhile, despite being a signatory of TRIPS, Indonesia has yet to pass a law concerning the commercial exploitation of valuable test data, which has been submitted to the authorities by drug firms

wishing to gain marketing approval for their products. The lack of an effective patent linkage system is also problematic as this can result in the approval of patent-violating products.

One of the most serious barriers to foreign drugmakers is the negative investment list, which was implemented in 2007. Under these regulations the amount of equity allowed by foreign companies investing in the Indonesian drug market is capped at 75%. This means that for all projects in the country, drugmakers have to seek local partners which will take a minimum of 25% equity in the project.

In addition, foreign companies are not allowed to participate in the drug distribution sector (with the exception of those already operating in the market). This matter is complicated further by the fact that all foreign drugmakers without a local manufacturing presence in the sector are classified as distributors. This impedes the entrance of new pharmaceutical companies into the market unless they are also willing to invest in local manufacturing sites.

Meanwhile, the Ministry of Health Decree 1010/MENKES/PER/XI/2008 (also known as Decree 1010), which was issued in November 2008, is expected to affect the ability of certain multinational pharmaceutical companies to obtain marketing authorisation for their products after 3 November 2010. Under Decree 1010, only companies registered as 'licensing pharmaceutical companies' will be allowed to obtain marketing approval. Several of PhRMA's member companies that do not manufacture products in Indonesia for the Indonesian market would therefore not qualify for this status. Although these companies will instead be classified as 'distributors', or 'PBF enterprises'; they nevertheless practice globally recognised good manufacturing and good distribution practices and provide high quality pharmaceutical products to Indonesian patients in the same manner as other leading pharmaceutical manufacturers that produce medicines in Indonesia.

Once Decree 1010 comes into effect in November 2010, PBF enterprises will be barred from the Indonesian market unless they either establish a factory in Indonesia or transfer sensitive IP to a local Indonesian company. Given the discrimination inherent in this decree, PhRMA has voiced its concern about its implementation and is pressing the Indonesian government to find a solution that will permit innovative pharmaceuticals to be traded, sold and distributed in Indonesia, regardless of origin.

Finally, PhRMA claims that multinational companies are unfairly targeted due to ambiguous tax laws. The inconsistent interpretation of tax regulations are resulting in a higher tax burden for MNCs, compared to local companies.

## Generic Drug Legislation

The Indonesian government is encouraging the increased provision of generic drugs in order to make healthcare more accessible in the country. In 2005, the Ministry of Health implemented a new decree that required any branded pharmaceutical product marketed in Indonesia to state its generic name directly

beneath its trade name. In addition, the generic name must be at least 80% of the size of the original and in the same font and colour.

The purpose of the legislation is to familiarise the public with the active ingredients of pharmaceuticals, making them better informed to choose generic equivalents when they become available. Multinational drugmakers have expressed their concern over such measures, claiming that bioequivalence studies in Indonesia do not comply with international standards. Therefore, consumers may purchase generic drugs that do not have the same quality, safety and efficacy as the branded original.

Foreign drug firms have also complained that such generic labelling contravenes pharmaceutical trademark rights as protected by the WTO-TRIPS agreement, to which Indonesia is a signatory. Furthermore, due to the fact that branded, original products are marketed exclusively by multinationals in Indonesia, these companies claim that the government is giving an unfair advantage to local generic firms.

However, the BPOM has recently enacted legislation whereby generic drugs that have been submitted for marketing approval must provide bioequivalence test data. There are currently only five laboratories in the country that have the technical capabilities to carry out bioavailability/bioequivalence studies. Foreign drugmakers remain concerned that other institutions used for such tests may not be adequate. All new generic drugs have required bioavailability/bioequivalence certification since the start of 2007.

## Labelling Requirements

All pharmaceutical products distributed in Indonesia must state their generic or chemical name, along with their brand name on the packaging. The generic name must be 80% of the size of the trade name and placed directly below it, utilising the same font and colour. However, a recent survey by the Indonesian Health Consumer Empowerment Foundation has claimed that the majority of drug companies are still not using generic labelling. Moreover, those that have adhered to the policy have generally failed to maintain the 80% size minimum.

Many drug companies have also been found in breach of regulations regarding price labelling. According to the measures, which took effect on August 7 2006, each product should be labelled with the maximum retail price as set by the Minister of Health. Again, this decree has yet to be widely followed. The Indonesian Pharmaceutical Association has even set retail prices higher than those set by the Ministry of Health, claiming that it had not been involved in discussions.

In August 2009, the BPOM issued new regulations that had the potential to impose excessive barriers against certain pharmaceutical products belonging to several of PhRMA's member companies. According to the 'Regulation Of Head Of The National Agency Of Drug And Food Control Republic Of Indonesia Number HK.00.05.1.23.3516' (also known as Halal Labelling Regulations), pharmaceutical, cosmetic,

and food products that do not conform to stipulated Halal requirements must now attach a new label and will be prevented from receiving a distribution licence, unless the Muslim clerical body, the Indonesian Ulama Council (MUI) declares that there is an 'emergency reason' to permit the distribution of the product. So far, the criteria for what constitutes an 'emergency reason' have not been issued, and both the healthcare industries and the general public fear that patients could face an interrupted supply or lose access to current treatments and vaccines once the regulations take effect.

## Counterfeit and Substandard Drugs

Indonesia has all the attributes to be a hotspot for counterfeits. Demand for imitation pharmaceuticals is high due to low spending power and rising drug prices. Smuggling is rife because the country is an archipelago that straddles several major trade routes. Regardless of pedigree, imported goods are perceived as being superior to locally made medicines. Finally, Indonesia is relatively close to China, which is the main source of counterfeit pharmaceuticals.

This view is supported by research conducted by Masyarakat Indonesia Anti-Pemalsuan (MIAP), Indonesia's Anti-Counterfeiting Society, which suggests that losses incurred by the state as a result of counterfeiting practices continues to rise each year and that OTC medications are the most widely imitated product. Based on a study conducted by the MIAP and the University of Indonesia's Institute for Economic and Social Research (LPEM-UI) between 2002 and 2005, counterfeit products in the footwear, textile, cigarette and pesticide industries were found to have resulted in IDR4.4trn (US\$459bn) being lost as state revenue. MIAP members include **Pfizer Indonesia**, **Unilever**, **Procter & Gamble Indonesia**, the **International Pharmaceutical Manufacturers Group** and **BP Indonesia**.

In the initial survey, pharmaceuticals were found to be the most counterfeited product, resulting in IDR607bn (US\$66.32mn) of lost revenue. According to MIAP Secretary-General, Justisia Perdana Kusumah, OTC drugs were still considered attractive counterfeit targets due to their vast retail market and high margin potential. This not only implied significant losses for pharmaceutical manufacturers, but also threatened brand credibility due to the risks posed to consumer health. Most counterfeited drugs were found to be cholesterol-lowering agents; as well as treatments for influenza, hypertension and slimming aids. The MIAP has therefore urged the Indonesian government to tighten regulations on drug circulation, and has also recommended that pharmaceutical companies review their supply chains should they find indications of their products being counterfeited.

In an attempt to address the problem, the MIAP recently launched a website where consumers could report cases of counterfeit products. Data from the National Police show that in the first six months of 2009, eight reports of counterfeiting were filed. However in 2008, the police recorded 18 such incidents, down from the 83 reported in 2007. Although the MIAP currently focuses on cases concerning its member companies, it has provided assurances that it will not turn down those concerning other manufacturers. Other MIAP members include **Epson Indonesia**, **Oakley Indonesia**, **Louis Vuitton**

**Moët Hennessey, Nestlé Indonesia, Aqua Danone, Shell Indonesia, Bintang Toedjoe and Quiksilver Indonesia.** Given the findings of its initial survey, the MIAP and LPEM-UI further announced that both institutions plan to carry out a similar study for the 2006-2009 period, with the results expected early in 2010.

Given the fact that the problem is regional, co-operation with neighbouring countries is essential. At the ASEAN-China Conference on Combating Counterfeit Medical Products in November 2007, concerned representatives from drug regulatory authorities, police, customs, pharmaceutical manufacturers, medicine wholesalers as well as health professionals were brought together for the first time.

However, a major barrier to reform is corrupt officials. According to a local private investigator in July 2007, clearing corrupt individuals from the office in charge of enforcing the legal distribution of drugs in the country would be a good start to tackling the counterfeiting trade. The investigator claimed that some authorities were paid up to IDR200mn (US\$22,000) to ignore the illegal trade.

An issue related to the counterfeit drug trade is that of substandard pharmaceuticals. Aid workers in Indonesia have claimed that tonnes of drugs and medical equipment donated to the country in the aftermath of major disasters are substandard, often being damaged, out-of-date or otherwise unusable.

For example, approximately 200 tonnes of medicines donated to help recovery from the Sumatran earthquake in March 2005 were incinerated for this reason. Local sources go as far as to claim that Indonesia has become a dumping ground for Western countries wishing to offload unwanted medicines.

## Free Trade Agreements

Despite the significant problems afflicting the pharmaceutical sector, it is hoped that opportunities to precipitate the growth of Indonesia's drug industry will be provided by the ASEAN free trade agreement (FTA), which is due to be fully implemented in 2011, when the 10% tariff on pharmaceuticals entering Indonesia will be reduced to zero. Expectations are that the FTA will significantly expand the country's drug market and boost the export of pharmaceutical products, although it will also increase competition. In late 2008, ASEAN reportedly introduced new requirements for the common technical dossier for the registration of pharmaceuticals for human use, which is based on the International Conference on Harmonisation (ICH) documents and is due to come into force in 2009.

In April 2009, ASEAN Economic Ministers signed the ASEAN Sectoral Mutual Recognition Arrangement (MRA) agreement for Good Manufacturing Practice (GMP). Under the terms of the accord, GMP certification and inspection reports received in one ASEAN member nation (in accordance with the MRA) will be accepted in all ASEAN countries without the need for additional testing. The MRA also calls for increased harmonisation of standards and reduced non-tariff barriers. ASEAN member nations will have until 2011 to fully implement the terms of the MRA.

Upon implementation of the MRA, GMP certificates and inspection reports that are issued in one country will be made available to all other ASEAN countries, thus eliminating the need for repetitive testing. This is expected to increase the market potential for drug manufacturers looking to sell in any of the ASEAN countries. The move will also facilitate post-marketing surveillance and product registration.

The accord stipulates that inspections should be conducted regularly, with member nations required to monitor their inspection services to ensure the harmonisation of standards across different member states. Adequate assessment of manufacturing facilities will also be required. The ASEAN member nations aim to fully realise their objectives for an ASEAN Economic Community by 2015, thus creating a trading bloc similar to the EU.

Indigenous firms could play a leading role in the regional market when the ASEAN FTA comes into full operation in 2015. Under this initiative, all ASEAN countries will be required to eliminate import duties, although founding members such as Indonesia, Brunei, Malaysia, the Philippines, Singapore and Thailand are required to end tariffs five years earlier. With over 200 drug firms, Indonesia's pharmaceutical industry has the potential to be more competitive than any other ASEAN market. Indonesian drug producers are understandably eager to enter into a potential US\$8bn new market, with a population totalling 600mn.

As part of efforts to expand the market potential for domestic pharmaceutical manufacturers, Indonesia's Pharmaceutical Association, GP Farmasi, announced in May 2009 that the domestic pharmaceutical sector hoped to establish foreign-owned factories locally by co-operating with drug manufacturers from ASEAN member countries. The aim is to establish an industrial base for raw materials in Indonesia. The Association has therefore proposed that the Indonesian government raise restrictions on the foreign ownership of raw-materials factories so as to attract investment from state-owned drug manufacturers within the ASEAN region.

Government legislation currently stipulates that foreign firms are only eligible for a 75% stake in domestic pharmaceutical companies, compared with 100% ownership permissible previously. As a result, many overseas pharmaceutical firms that have wanted to invest locally have abandoned their plans as a result of government restrictions on foreign investment. It is hoped that such co-operation could end the country's dependence on raw materials which are presently imported primarily from China and India. Domestic pharmaceutical firms currently receive government subsidies to purchase raw materials for the production of generic drugs. This, it is argued, is intended to stabilise prices and reduce the cost of raw materials.

Data produced by GP Farmasi shows that the market value for pharmaceutical products in the ASEAN region could rise to US\$8bn by the end of 2009, compared with US\$7bn in 2008. Indonesia holds 34% of the pharmaceutical sector's total projected market value of the ASEAN region this year, followed by



Thailand which holds 26%; the Philippines with 25%; Malaysia with 8%; and Singapore with 7%. About 40 firms from GP Farmasi's 208 members dominate approximately 80% of the domestic market. The Association has projected that the value of the domestic pharmaceutical market would rise to IDR28trn (US\$2.96bn) this year, up from IDR27trn (US\$2.85bn) in 2008.

Through its ASEAN membership, Indonesia has negotiated bilateral deals with partner countries. China is due to complete an FTA with ASEAN by 2010, representing new business opportunities as well as threats to Indonesia. An FTA between ASEAN countries and Australia and New Zealand was signed in February 2009, while a deal with India is also being implemented, having been approved by the Indian cabinet in July 2009. An agreement with Japan is already in force, implementing a lower 5% tariff for medicines.

The economy of the regions included in the China-ASEAN Free Trade Area (CAFTA), is predicted to involve 1.8bn consumers, US\$6trn in GDP, and US\$4.5trn in trade, once the accord is fully executed. The implementation of the CAFTA will cause the average goods tariff from ASEAN countries to China to be reduced from 9.8% to 0.1%; while in return, the six original ASEAN members, including Indonesia, will reduce the average tariff on Chinese goods from 12.8% to 0.6%.

In spite of its huge potential, Web Warouw, Secretary-General of the People's Health Council (DKR), voiced his concerns that the CAFTA will create tough competition that could disadvantage the access Indonesians have to quality healthcare. Warouw believes the FTA would encourage China to flood the country with drugs that could provide cheaper alternatives for Indonesian patients, but whose quality and legality might prove to be questionable. The prospect of having more private and foreign-owned hospitals in the country after the implementation of the CAFTA could also make the price of healthcare more volatile.

Echoing such sentiments, the Head of Indonesia's Pharmaceutical Entrepreneurs Association, Anthony Sunarjo, believes the ASEAN-China FTA has the potential to threaten Indonesia's domestic pharmaceutical industry, especially small-and-medium-size companies within the sector. In his view both India and China now have the capacity to produce cheaper medicines as a result of their large economies of scale and scope, as well as a more advanced scientific base. The association has therefore asked the government to delay the implementation of the ASEAN-China FTA given its potential impact on the 200 domestic pharmaceutical companies that comprise Indonesia's pharmaceutical sector. Of the 200 pharmaceutical companies, just 20 can be deemed to be 'major players', thus holding 80% of the total market currently worth approximately IDR30trn (US\$3.32bn).

Adding to the debate, Siti Fadilah Supari, a former Minister of Health said she believed that the government should enforce a number of regulations, such as the 2008 Health Ministry regulation on drug registration, or the 2009 Hospitals Law to combat the unwanted effects of the FTA. The 2009 Hospital Law stipulates the necessity of regular hospital assessments and the government's obligation to guarantee

healthcare for the poor. Elsewhere, Huzna Zahir from the Indonesian Consumer Protection Foundation (YLKI) said the possible flood of drugs and increase in health services could have both negative and positive impacts. While the possibility of uncontrolled quality was an obvious disadvantage, intense foreign competition had the potential to encourage the local health industry to improve its own standards.

## Pricing Regime

The country's pricing and reimbursement systems further reflect the market's underdeveloped status, with considerable restructuring and modernisation required. More specifically, there are no pricing controls for private-sector medicines, while recent public-sector policy has been defined by the economic crisis of 1998. In response to the collapse, the government markedly reduced the price of drugs in order to enable hospitals and pharmacies to purchase essential supplies, and granted subsidies to local producers to enable the import of essential raw materials.

However, inflation and higher US dollar rates have resulted in price inflation, which has not been kept in check by the regulator BPOM. Drug price increases every few months became the norm, while in 2001 the industry was given a free hand to raise prices almost at will. According to the Health Minister Supari, the prices of medicines in Indonesia are among the highest in the world. This means that many on low incomes cannot afford even the most basic pharmaceuticals, such as analgesics and antibiotics. Supari blames 'mafia syndicates' and the 'neo-liberal' economic system.

Prices vary between the private and public sectors, as well between different regions of the country, suggesting that distribution and related costs are taken into account. Prices of generics also vary, although they are generally much lower than those of the original brands. In addition, the cheapest generics are not always the most commonly dispensed drugs. The total VAT is 20%, with 10% added on to retailers' and distributors' prices. Overall, the mark-up on medicines is between 54% and 88% by the time it reaches the patient.

OTC pricing is free and controlled by market forces, which have kept the prices low due to the limited patient purchasing power. Non-prescription items cannot be reimbursed.

The government considers the manufacturer's suggested retail price as a determining factor in granting marketing approval for new products. Consequently, the request for a price deemed too high can lead to a rejection or a delay in marketing approval. In 2005, the government proposed the imposition of formal price controls, although no changes have been announced yet.

## Price Cuts

In December 2004, the government implemented price cuts ranging between 10% and 50% on 29 major drugs in order to control imported raw materials costs, which were phased out in 2006. The reductions

affected best-selling drugs, including antibiotics such as amoxicillin and erythromycin, thereby also having an impact on many indigenous manufacturers. The decision significantly reduced profit margins, particularly among manufacturers of generic products – the government's primary target. Selling prices on the antibiotic ciprofloxacin (marketed by German drugmaker Bayer as *Cipro*) fell by 50%, while most other cuts fell into the 10-35% range.

In July 2006, a new government regulation related to prices came into force, with the association of local pharmaceutical producers deciding to take pre-emptive action to voluntarily lower the prices of 34 active pharmaceutical ingredients (APIs) (affecting around 1,400 prescription products on the market). The price cuts were in the 10-70% range of the original price. Earlier the same year, the government reduced the prices of certain unbranded generics by up to 50%.

This was followed by a price cut in November 2006, in the largest move of its kind witnessed in the country, which affected some 458 medicines. The drugs identified in the decree include most of those on the NEDL, yet many 'non-essential' but effective treatments remain untouched. US drug industry association PhRMA has acknowledged the government's concerns over drug prices and its desire to introduce formal price control structures. Nonetheless, PhRMA has asked to be included in the consultation process in order to help find the best way to promote quality care without stifling the environment for innovative pharmaceutical products. More recently, in December 2009, the Ministry of Health announced that it would lower the price of 106 generic drugs while at the same time the cost of 33 others would be increased. Despite these changes, the price of 314 other generic medications was to remain the same. The changes formed part of the government's review of prices relating to all 453 generic drugs currently available on the market. It followed reports that 80 sought-after generic drugs had disappeared from the local market, thus seriously affecting the healthcare services of Central and Eastern Indonesia. Due to the country's unique composition, the distribution of medicines is expensive because 98% of Indonesia's pharmaceutical industry is located on the island of Java.

Despite increasing government regulation in this area, the pharmaceutical industry is reportedly failing to implement a number of measures designed to reduce drug prices in the country. The Ministry of Health issued several decrees in 2006, obliging drugmakers to lower prices and place price labels and generic names on medicines. Many companies are not taking any action to lower their prices, resulting in a situation where a number of product prices are actually between five and 27 times higher than the official price, which leads to distortions. For example, the antibiotic ceftriaxone costs US\$25.48 per gram in Indonesia, yet costs no more than US\$14.62 per gram in neighbouring countries such as the Philippines, Singapore, Malaysia and Thailand. Consequently, drug prices in Indonesia are exorbitantly high, with only around one-quarter of patients able to afford their prescriptions.

A key issue is that the domestic pharmaceutical industry lacks the capability to develop raw materials; therefore, over 90% of the 1,300 raw materials used to manufacture drugs in Indonesia have to be

imported, mainly from India and China. Appreciating currencies and factory closures in these areas, combined with Indonesian import tariffs (which can be as much as 6.5-12.5%), have resulted in increased costs and reduced margins.

## Reimbursement Regime

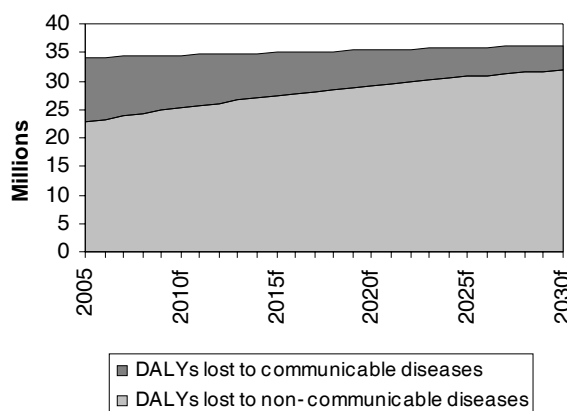
The fact that there is no private insurance available in the country means that most patients have to foot 100% of their drugs bill. In addition, patients are not reimbursed for their pharmaceutical expenses. Although the government operates a National Essential Drugs List (NEDL), it is much smaller than the standard WHO-recommended list. As a result, only about 50% of the drugs on the list are readily available throughout the country. The list comprises solely of generics, as branded products are deemed too expensive, which in practice leaves certain conditions untreated. Additionally, the government continues to encourage generic substitution as a means of reducing the overall drugs bill.

## Industry Trends and Developments

### Epidemiology

Indonesia's healthcare indicators have improved in recent years, in line with economic development. According to President Yudhoyono, better health has been the result of government policies to improve access to medicine and improved nutrition. Life expectancy has risen from 66.2 years in 2003 to 69.4 in 2006. Over the same period, infant mortality has decreased from 36 in every 1,000 births to 32. People living longer means that fewer individuals of wage-earning age are dying, while more children surviving results in a buoyant workforce. However, Indonesia – which is cursed by endemic poverty among a large proportion of its population – has a long way to go before it emerges from the ranks of developing countries.

**Burden Of Disease Projection  
2005-2030**



*f = forecast. DALYs = disability-adjusted life years. Source: BMI's Burden of Disease Database (BoDD).*

Cancer and cardiovascular disease represent main causes of mortality in Indonesia. According to figures from the WHO Regional Office for South Asia, cancer is responsible for 6.6% of total recorded deaths in Indonesia, higher than elsewhere in the region. Cervical cancer is the most commonly reported type of cancer in women, with the high incidence of smoking blamed for rising rates of lung tumours.

Recent studies indicate that one Indonesian woman dies every hour from cervical cancer as a result of poor screening coverage in the country. It is thought that less than 5% of women in Indonesia regularly take a Pap smear test – the screening process for cervical cancer – compared with the WHO recommendation of 80% per population.

Data from the Indonesian Cancer Foundation (YKI) shows that cervical cancer kills 25 women every day, with the 40 to 45 new cases detected daily making it the most deadly cancer among Indonesian women. According to the Head of the YKI, Sumaryati Aryoso, many women, especially low-income earners, are concerned about the cost of screening and vaccination. At present, a Pap smear test conducted in hospitals costs approximately IDR100,000 (US\$9.70); while the three-shot HPV vaccine costs IDR1.8mn (US\$190.88). Given the high costs involved, one of the main priorities of the YKI is to provide a more

affordable screening and vaccination program. The YKI currently offers screening and vaccine programs for all types of cancer at half cost.

According to Tofan Widya Utami, an obstetric gynaecologist from the University of Indonesia, one the principal reasons for poor early detection is that cervical cancer in its early stages is mostly asymptomatic and therefore goes unnoticed. Because of this, about 70% of cervical cancer sufferers in Indonesia only seek treatment once the disease has reached a terminal stage. Lack of information about the disease coupled with fear of a cancer diagnosis has also contributed to low levels of screening and early detection. Statistics suggests that about 8,000 women currently suffer from cervical cancer, with the mortality rate heading over 60%.

Over the past five years, there has also been an increase in cervical cancer among younger women, possibly due to changes in sexual behaviour. Statistics show that the number of women in their early 20s who have been diagnosed with the disease has increased year-on-year. The need for the Indonesian government to introduce screening regulations to reduce the number of cervical cancer patients is therefore widely advocated given that regular Pap smear screening (conducted once every year) can help detect precancerous changes, thereby making the disease 100% curable.

Malnutrition also remains a major health concern in Indonesia. An October 2009 survey conducted on two islands in the Thousand Islands regency of Indonesia has revealed a bleak picture of poverty and neglect, with malnutrition and anemia emerging as areas of major concern. The Yayasan Kusuma Buana Foundation (YKB), a non-Government Organisation (NGO) that focuses on health and community building, in cooperation with the International Pharmaceutical Manufacturers Group (IPMG) and the Thousand Islands regency, conducted two month-long surveys to ascertain the levels of anemia among the local population. One study was conducted on children under the age of five, pregnant women, lactating women and mothers with children under the age of five; while another was carried out on students from Panggang Island and Pramuka Island. The survey on anemia was conducted on students in five schools and eight Integrated Community Health Posts (Posyandu), and involved more than 1,800 respondents.

The results of the first survey indicated that the prevalence of anemia cases among pregnant women was 75.5% – a sharp rise over the national average of 50%. However, after 12 weeks of health education and treatments using supplements, the figure decreased to 36.3%. The results of the second survey, conducted in February and March 2009, revealed that the prevalence of infant anemic cases remained at 80.8%. It also indicated that anemia among children under the age of five stood at 66.1%.

In addition, the foundation also conducted a survey on nutrition on students from 12 elementary schools in the area. With more than 2,300 students participating in the survey, the results showed that as much as 28.4% of respondents suffered from chronic malnutrition. The main causes of this were found to be a lack of knowledge about proper nutrition and a balanced diet. Vegetables are scarce on the islands, with most

having to be imported from the capital, Jakarta. This in turn led to increased prices for such commodities. Other factors that affected malnutrition and anemic conditions included sex and gender, with some families prioritising males in terms of nutrition. The Thousand islands regency, which comprises up to 897.71 hectares of land, has a current population of 20,736. It became a regency in 2001 after previously being part of North Jakarta's municipality.

However the prevalence of malnutrition is not confined to Indonesia's outlying regions. Even in its capital city, Jakarta, between January and March 2008, 34 cases of malnutrition were reported – most of which were children. A report published by the Ministry of Health in 2007 indicated that there were 4.1million cases related to nutrition and malnutrition at the national level.

In addition, common diseases such as dengue fever, tuberculosis (TB), malaria and food poisoning still exist in varying degrees in different provinces. It is thought that over 1,500 children die every day from treatable diseases such as tuberculosis, malaria and pneumonia.

In an effort to combat the prevalence of malaria, the Ministry of Health recently initiated a Malaria Elimination Programme, aimed at eradicating the disease by 2030. This follows the first malaria elimination campaign which was introduced more than 50 years ago. About one to two million people contract malaria each year, resulting in about 100,000 deaths nationwide. Slow progress has been made to reduce the prevalence of malaria and tuberculosis in Eastern Indonesia compared to the Java and Bali regions.

Despite eight recent deaths and cases of alleged poisoning of 800 residents in the regency of Bandung, West Java, following the consumption of anti-filarial medication in November, the Ministry of Health announced that it will resume its lymphatic filariasis mass medication programme. The Minister for Health, Endang Rahayu Sedyaningsih, stressed that mass medication was needed because the 40mn people currently infected with the microfilarial worm were at risk of infecting a further 125mn people in areas susceptible to the disease. The minister has assured the public that the casualties and cases of alleged poisoning that have arisen in Bandung were not related to the mass medication programme. Under the auspices of the Ministry of Health, the eradication programme will resume in 2010, covering a population of 57mn in 98 regencies and mayoralities across the country. The figure also includes about 2.7mn residents of Bandung above two years of age. As of October 2009, a blood test survey revealed that microfilarial worms had infected the blood of 19% of the country's population. Patients suffering from one symptom – elephantiasis, or skin and underlying tissue thickening, have been found to be spread across 386 cities and regencies in Indonesia.

According to government guidelines, the anti-filarial medicine consists of diethyl carbamazinecitrate, albendhazo and paracetamol, designed to reduce fever after consumption of the medication. The treatment

has not been administered to children under the age of two; pregnant and breast-feeding mothers, as well as people suffering from heart disease and diabetes.

The Head of the West Java Health Office, Alma Lucyati, announced that the mass anti-filariasis medication program would be administered in 24 cities and regencies in the province in 2010. West Java has so far recorded 980 patients suffering from acute lymphatic filariasis in 267 villages and 147 districts in 24 cities and regencies. Of this, 11 areas have also been recorded as susceptible to the disease including, Bekasi city and regency, Bogor city and regency, Depok city, Karawang, Purwakarta, Subang, Tasikmalaya, Kuningan and Bandung regencies.

Alongside communicable diseases, Indonesia also faces the threat of Non-Communicable Diseases (NCD), including cardiovascular disease, diabetes and hypertension. The 2007 Basic Health Research study (Riskesdas) conducted by the National Institute of Health Research and Development (BALITBANGKES) indicated that 31.7% of Indonesians suffered from hypertension (the most common NCD); while 7.2% suffered from cardiovascular disease. Studies have indicated that the incidence of diabetes is also on the rise as a direct result of the increasing prevalence of Western dietary and lifestyle patterns. The condition is indirectly responsible for a growing number of other health problems such as heart attacks and circulatory disorders amongst the population.

Data released in November 2009 suggests that approximately 13% of first-time smokers in Indonesia are junior high school students. The survey, which was conducted by Surakarta Health Agency's Respiratory Illness Division across five major cities in Indonesia, including Surakarta in Central Java, also revealed that 89% of young female employees across the survey region were smokers. Overall, the findings of the study have indicated an alarming rise in the number of smokers in general. The agency believes the Indonesian government's anti-tobacco campaign has been ineffective primarily due to the authorities' refusal to sign the international convention on tobacco control. Cigarette manufacturers currently contribute significant resources to state revenue, while thousands of workers rely on the industry for employment.

When taken from an international perspective, levels of health in Indonesia are still below that of its South-East Asian neighbours. Basic health indicators, such as Infant Mortality Rates (IMR) and Maternal Mortality Ratio (MMR), provide the clearest evidence. In 2007, Indonesia's IMR was 34 per 1,000 live births; while its MMR was 228 per 100,000 live births. Although the trends for both indicators have shown signs of improvement, the figures have not changed significantly in recent years. In terms of communicable diseases, Indonesia is ranked third in terms of tuberculosis, after India and China.

With less money invested in promotion and prevention programs, many people rely on healthcare services without a good understanding of the benefits of prevention. In 2009, the Ministry of Health's budget amounted to IDR18trn (USD\$19.21bn). Of this total, 48.5% was allocated for curative and medicine



operational costs; 15.8% for public health; and only 7.7% for communicable and non-communicable disease programs.

## Recent Public Health Developments

Health experts have been calling on Indonesian authorities to increase spending on mother/child services. Healthcare leaders are pushing the country to align services to the UN's Millennium Development Goals (MDGs), which are justifiably biased towards improving welfare of females. Three particular targets have been identified:

- Reducing the distance between place of delivery and healthcare facilities, presumably through the establishment of more local hospitals and clinics;
- Upgrading facilities to more modern standards to include technology such as ultrasounds; and,
- The provision of adequate free treatment to those who cannot afford it.

However the attainment of such goals appears to be in jeopardy as a result of the corruption endemic in Indonesia's healthcare system. Patients frequently pay bribes to receive treatment, numerous layers of bureaucracy consume resources and pharmaceutical manufacturers are frustrated by a lack of transparency. Although other developing countries have similar problems, **BMI** notes that the situation in Indonesia shows few signs of improvement.

A key area of concern is abuse of the *Surat Keterangan Tidak Mampu* (SKTM) scheme, which provides affordable healthcare to those on low incomes. Under the programme, a government sub-district chief determines if an individual is living in poverty and subsequently issues them with a letter. The applicant has an interview with Health Agency officials to establish the appropriate amount of payment relief. Patients then visit a public or private hospital to receive subsidised medical treatment. Most SKTM members are eligible to receive a 50% reduction in fees. However, a survey conducted by Indonesia's Corruption Watch found that sub-district officials often requested IDR100,000 to IDR400,000 (US\$10.60 to US\$42.42) for a letter, regardless of the applicant's financial status. This widespread problem means that some of the poorest people in Indonesian society cannot access healthcare, thereby leading to a worsening of their medical conditions.

Syamsul Arifin, a director of state-owned pharmaceutical company **Kimia Farma**, believes that Indonesia will not achieve its 2015 MDGs, in part due to corruption in the healthcare sector. At a recent conference on corruption eradication, Arifin said that slack regulations and corrupt officials had allowed unsafe medicines into the supply chain. This compromised public health and made certain that some of the country's MDGs – such as reducing child mortality rates by two-thirds – would become impossible

targets. According to the WHO, Indonesia spent 2.48% of its GDP on medical services in 2007. This figure is below both the Asia Pacific (4.88%) and global (6.72%) averages.

**Table: UN Millennium Development Goals**

- Eradicate extreme poverty and hunger
- Achieve universal primary education
- Promote gender equality and empower women
- Reduce child mortality
- Improve maternal health
- Combat HIV/AIDS, malaria and other diseases
- Ensure environmental sustainability
- Develop a global partnership for development

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Source: UN

In addition to improving maternal care, the Indonesian government is also urged to take steps to combat HIV/AIDS, malaria and other communicable diseases, primarily through prevention but also through treatment. Greater utilisation of public health centres (*puskesmas*) and increasing the frequency of public education campaigns have been proposed to alleviate the problem.

To this end, the government has achieved considerable success in combating the prevalence of Hepatitis B in Indonesia. It is anticipated that the disease will decline gradually in future once the benefits of the government's immunisation initiative and awareness programs take effect. However, the number of detected Chronic Hepatitis B (CHB) patients is expected to rise as a result of a growing urban population which will have access to medical facilities. With the mounting number of diagnosed CHB patients, the number of patients treated will also increase, thereby boosting the uptake of anti-virals for treating the disease.

Research has shown that government initiatives directed at routine childhood vaccinations for Hepatitis B have reduced the incidence of the disease in children and adolescents in the under 15 year age category - a trend which is expected to have an overall impact on the incidence of Hepatitis B Virus (HBV) carriers in the medium-to-long term. As a result of enhanced patient awareness and diagnosis, a larger patient base will therefore be available for treatment. Patient access to existing, as well as to new nucleoside analogues is currently improving, with more patients being expected to gain access to effective treatment.

The continuous and rigorous government initiatives, such as the 'Healthy Indonesia 2010' program aims to eliminate Hepatitis B, along with other significant diseases. At present, nucleoside analogues are the preferred choice of treatment for physicians in Indonesia due to their efficacy, cost and lower resistance.

The number of patients diagnosed and treated is on the rise as a result of greater awareness, improved diagnosis and government-sponsored programs.

Besides therapeutics however, vaccines are also considered a potential market for expansion. A number of domestic as well as multinational pharmaceutical companies compete in the therapeutics and vaccines market in Indonesia. While western drugs continue to dominate the market with an overall share of 85%, in urban areas, physicians suggest that almost 100% of the drugs used for treatment are of western origin.

It is thought that nucleoside analogues are likely to continue to experience strong growth as most clinical trials are conducted in the area of nucleoside analogues. As a result, there are significant opportunities for further expansion in the nucleoside analogues, interferons, and vaccines markets. New entrants, with aims compatible with the objectives of the government, are likely to be encouraged.

With regard to HIV/AIDS however, Indonesia has one of Asia's fastest growing HIV rates with up to 290,000 infections out of a population of 235mn, a trend that is fuelled mainly by injecting drug users and prostitution. However, the country's prevalence rate of 0.1% remains small compared to the Asian average (0.4%) and sub-Saharan Africa (6.1%). Figures released by the National Trainer Care, Support and Treatment of Integrated Management of Adolescent and Adult Illness (IMAI) for HIV/AIDS in November 2009 suggest that 300 cities and sub-districts across Indonesia will have five million cases of HIV/AIDS by 2010. The number is based on an estimation of HIV/AIDS sufferers who have visited hospitals in the country. However, it is thought that this figure accounts for no more than one tenth of the total number of people infected with the deadly virus.

According to IMAI's Head, Ronald Jonathan, the number of reported cases is expected to reach between 93,000 and 130,000 by 2010, marking a mere 5-10% of total number of sufferers in Indonesia. Data gathered since the 1980s to September 2009 indicate that Indonesia has about 18,442 cases of HIV/AIDS, with a male-female ratio of 3:1. The most recent data suggests that sexual intercourse has now become the most frequent method of spreading the disease, accounting for 50% of the total number infected with the virus. Contraction through the use of syringes now accounts for 40.7%. In addition, the data shows that the spread of HIV/AIDS among certain groups such as homosexuals and transsexuals is only 3-4%. It is thought that people aged 20-39 years of age are at the greatest risk of contracting the disease.

In April 2009, the National AIDS Commission (KPA) announced that in order to guarantee a continuous supply of antiretroviral (ARV) drugs for patients with HIV/AIDS, Indonesia will in future receive donations in the form of drugs instead of cash payments. Under the new arrangement secured with the **Global Fund for AIDS, Tuberculosis and Malaria**, aid from the international funding organisation would be delivered in the form of the drugs themselves given that interruptions to the supply of ARV drugs has been a longstanding problem in the country. Hospitals have frequently complained that interruptions to the supply of treatment has often endangered the lives of patients as it triggers a resistance

to the drugs, which in turn forces patients to switch to higher-dosage ARV medication. Such treatment is not only more difficult to obtain, but more expensive and potentially more harmful to the patient. At present, funding to fight HIV/AIDS across Indonesia comes from the state budget as well as from donations from the global fund. For 2009, the Ministry of Health earmarked IDR39bn (US\$41.24mn) to help fight the spread of the disease and to provide free ARV drugs for treatment. For its part, the global fund has committed IDR22bn (US\$23.26mn) for the same program.

Under the new scheme, Indonesia would join the global fund's **Voluntary Pooled Procurement Program (VPP)**, which involves drug donations instead of cash. The fund would also assist in the provision of better drug storage facilities, as well as the setting up of a more efficient distribution system. It is hoped that the new arrangement would enable Indonesia to obtain more ARV drugs given that the VPP program is able to buy the medicine at a cheaper price under an agreement set up by UNITAID. In 2008, ARV drugs were 16% cheaper through the VPP program than the lowest priced medication available on the market. At present, ARV drugs can be obtained for free at 122 referral hospitals and 26 satellite hospitals across the country, which provide cover to the 25,000 HIV/AIDS patients in Indonesia.

However recent studies suggest that limited public awareness programs on the spread and prevention of the HIV/AIDS virus has been one of the main contributing factors to Indonesia's high prevalence of HIV/AIDS within the Asian region. Posters and advertisements made on public service mediums appear to have had a limited impact on providing the general public with what should be known about the disease. It has also been found that many have even misunderstood the messages that the posters on HIV/AIDS try to convey. This has been especially true among younger members of the population. The findings were made public at an AIDS awareness campaign held at the Foreign Languages High School in July 2009.

According to *The Jakarta Post*, a seminar commemorating World Haemophilia Day on April 16 2009 ended with an appeal to the Indonesian government to provide sufficient medical facilities for the treatment of haemophilia. Haemophilia is a hereditary genetic disorder that damages the patient's ability to control blood coagulation. The disease can cause death or result in disability if proper treatment is not provided at early stages. Around 1 in 4,000 children are born with the condition.

Furthermore, Terawan Agus Putranto, an Indonesian health expert, has stated that about 42,600 new cases of liver cancer are registered in Indonesia each year. He said that most of the cases are caused by hepatitis, which is a prevalent disease among local people. He added that the main reason behind the spread of hepatitis is careless use of needles and unchecked blood transfusions. BMI's Burden of Disease Database (BoDD) estimates that the number of disability-adjusted life years (DALYs) lost to liver cancer was 206,109 in Indonesia in 2008. We forecast that this should increase by approximately 15.01% to 237,055 DALYs by 2015, and further by 19.11% to 282,360 DALYs by 2030.

In March 2009, according to The Press Association, Siti Fadillah Supari, Indonesia's health minister, stated that the government has decided to stop childhood vaccination programmes against meningitis, mumps and several other diseases. This is mainly due to the government's belief that pharmaceutical companies are using the country as a testing place for drugs, although the move will clearly impact childhood mortality and morbidity levels.

## Avian and Swine Flu

The first cases of avian flu were recorded in Indonesia in October 2003, with further outbreaks reported throughout subsequent years. By the end of April 2008, Indonesia recorded 107 human deaths from avian flu, thus having by far the highest mortality rate from the disease in the world. It accounts for nearly half of the 240 deaths worldwide. Most worryingly, in contrast to other affected nations the death rate is continuing to climb steadily. The government has restated its commitment to fighting the disease but has been notably unwilling to invest its own resources, relying instead on international aid and recently putting in a request for US\$900mn in multilateral grants.

Local sources claim that part of the problem is that available funding is being misspent. Instead of focusing efforts on humans, the authorities should be concentrating on eradicating the disease among livestock. However, farmers are being offered scant compensation for each bird destroyed. Additionally, industry observers estimate that the country needs approximately US\$900mn for a three-year flu eradication programme, although pledged international donations amount to only US\$50mn. A national avian flu commission was established in March 2006 to co-ordinate the country's efforts to tackle the disease, but has so far has had limited success.

However, in early 2009 the major threat changed from avian to swine flu, following an outbreak of the virus in Mexico, and fears of a global pandemic. As reported in May 2009 by The Jakarta Post, the Indonesian government is taking measures to combat the risks of a swine flu pandemic by stocking 3mn dosages of oseltamivir, an antiviral drug. The Ministry of Health has also decided to distribute antiviral medications to hospitals and healthcare centres, as well as trying to secure more drugs in case the seriousness of pandemic increases.

Symptoms of swine flu include lethargy, fever, coughing, sneezing, diarrhoea, nausea and vomiting. Swine flu in humans is most contagious during the first five days of the illness, although some people – most commonly children – can remain contagious for up to 10 days. Public health agencies first detected localised incidences of influenza-like illnesses in Mexico in late March 2009.

According to data released from the Ministry of Health, the first case of the swine flu virus was detected in Indonesia on 24 June 2009. Since this time, cases of swine flu have been detected in 15 provinces in the country, including the provinces of Bali, Banten, Yogyakarta, Jakarta, West Java, Central Java, East

Java, South Kalimantan, Riau Islands, North Sulawesi, South Sumatra, North Sumatra, East Kalimantan, South Sulawesi and Jambi.

The outbreak of both the avian and swine flu viruses has once again underlined the importance of having clearly defined collaborative agreements in the pharmaceutical sector as a means of dealing with the threats posed to human life. Given the urgency and potential of the latest swine flu outbreak, the Indonesian government, together with state-owned pharmaceutical company **PT Bio Farma**, announced that it plans to start producing vaccines for the H1N1 and H5N1 strains of influenza by November 2010. The announcement was made at the inauguration ceremony of Airlangga University's Avian Influenza Research Center (AIRC), located in Bandung. The Indonesian government has allocated IDR1.3trn (US\$141.55mn) to fund the research, development and production of the vaccines. Bio Pharma will begin clinical trials in March 2010 and will start producing the H1N1 vaccine by November of the same year. The aim is to produce about 20mn doses in the first year of production.

According to the Head of the centre, C.A. Nidom, Airlangga's team of researchers had begun work on the vaccines in 2006 after the Ministry of Health had handed over five strains of the avian flu virus. In August 2009, the Ministry handed over a further six strains of the influenza A virus. Following the research, the 13-member team comprising researchers from Airlangga University and Bio Farma finally succeeded in creating and developing seed vaccines for both infectious diseases. Nidom also expressed optimism that the vaccines would be effective in preventing the spread of the diseases among humans, given that his team had found the vaccines to be effective in trials conducted on marmots, mice and monkeys. There is growing confidence that Bio Farma would be successful in mass producing the vaccines since it is the only vaccine producer in Southeast Asia.

The vaccine factory will be established simultaneously with the development of a chicken farm in Lembang, North Bandung. The purpose of the farm is to supply clean, embryonated eggs as a medium in which the virus strains would be grown. The factory, which will use Japanese technology, will require 35,000 eggs a year to successfully implement the project. To meet the demand, the Indonesian government has therefore pledged to import 48,000 White Leghorn samples from Japan. Once successfully developed, the vaccine will be offered first to researchers and paramedics as they are critically exposed to the viruses in their line of work.

If the current swine flu outbreak progresses into a pandemic, the social and economic impact will be immense. Many millions of people will die and global GDP will contract significantly. While certain drugmakers and medical device manufacturers will profit, all other pharmaceutical companies will see sales decline sharply. Both government and personal spending will contract, resulting in reduced demand for both prescription and OTC medicines.

It is important to note that many other diseases can cause pandemics. HIV/AIDS has led to the deaths of more than 25mn people since it was first recognised in 1981. Malaria, while restricted to subtropical and tropical regions, results in over 300mn cases and 1mn fatalities each year. In addition to influenza, future pandemics may include the Ebola virus, antibiotic-resistant microorganisms (or 'superbugs'), severe acute respiratory syndrome (SARS), and the oft-forgotten bird flu.

## International Avian Flu Partnerships

In September 2009, the National Committee for Bird Flu and Pandemic Diseases, in cooperation with the United Nations Children's Fund (UNICEF), distributed 50,000 packages of free antiseptics, including hand sanitisers and tissues at public places in Indonesia's capital, Jakarta. Locations targeted in the scheme were the Pasar Senen train station, Tanjung Priok port, Gambir train station, Pulogadung bus station and Soekarno-Hatta international airport. The programme forms part of UNICEF's efforts to minimise the spread of pandemic diseases such as bird flu and swine flu (H1N1) within the country

The Australian government is funding 10,000 doses of the anti-viral treatment *Tamiflu* (oseltamivir), manufactured by Swiss drug major **Roche**, in order to help fight the outbreak of avian influenza in Indonesia. Australia has so far allocated AUD133mn (US\$100.77mn) over the past two years to combat both avian flu and severe acute respiratory syndrome (SARS) in the Asia Pacific region. In November 2005 the Ministry of Health declared that *Tamiflu* would be produced only for government use (having obtained authorisation from Roche) and not for the entire Indonesian population. The government has assigned production rights to state-owned drugmaker Kimia Farma.

In March 2007, the Ministry of Health announced that it would resume the sharing of H5N1 avian influenza virus samples with the WHO's Collaborating Centres for analysis and preparation for vaccine production. The collaboration had been halted amid criticism that the developing countries are providing the virus samples, but are unlikely to receive the resulting vaccines produced by commercial companies. The WHO welcomed the move, encouraging efforts to link vaccine manufacturers in both developed and developing countries, in a bid to accelerate the transfer of influenza vaccine manufacturing technology. Subsequently, in April 2007, Indonesia announced that it planned to work with Egypt – which has a more developed pharmaceutical industry – to develop a human bird-flu vaccine.

Indonesia and Singapore recently agreed to collaborate on a pilot project aimed at eradicating the threat from avian flu. The undertaking, complying with WHO principles, will be centred on a specific region in Indonesia. Similarly, Indonesia has accepted the offer of co-operation by the European Commission on Health and Consumers Protection (ECHCP) in areas pertaining to surveillance and research. Discussions between the ECHCP delegation and the Indonesian government highlighted the urgent need to improve facilities for the handling of animal health, including the provision of laboratory equipment and enhancing the skills of laboratory personnel. In the meantime, Indonesia will continue with the selective elimination of animals suspected of suffering from avian flu.

However, according to Indonesia's National Committee for Bird Flu Control and Pandemic Preparedness, the number of countries and institutions donating money to combat bird flu has decreased over the past three years. During a bird flu conference in Beijing during January 2006, a total of 35 countries pledged to donate money to combat the disease. However, only 17 had actually provided funds at the Bamako conference in December of the same year. Just nine institutions made donations a year later during the New Dehli (India) conference, and barely six donated at the recent Cairo (Egypt) event.

## Healthcare System

Indonesia's healthcare system is decentralised and organised on a number of levels, including provincial, district and sub-district (municipal). Each sub-district is served by at least one health centre run by a doctor and a few sub-centres, usually staffed by nurses. Most of the centres have mobile service units.

At village level, preventative services are provided by the integrated Family Health Post. Midwives employed by the services are particularly focused on the improvement of child and maternal health.

Only a very small percentage of the population has health insurance and the vast majority is reliant on the public healthcare system. Health expenditure as a percentage of GDP has been falling in recent years, with the trend expected to continue throughout the forecast period. Unless patient purchasing power improves proportionally, drug coverage will worsen over time.

Healthcare facilities are severely under-funded and in many cases, do not meet prescribed standards. For example, recent findings suggest that although strict hand hygiene is prescribed as standard procedure for healthcare workers, the compliance rate in Indonesia is currently low, thereby heightening the risk of healthcare associated infections. This is despite the fact a ministerial decree containing managerial guidelines on preventing and controlling infections in hospitals and other healthcare institutions had been issued in 2007.

A case in point is the Dr Cipto Mangunkusumo General Hospital. According to its Director, Akmal Taher, the hospital adopted a patient safety programme in 2008, which included a hand hygiene protocol. However, only between 20- 40% of hospital workers adhered to the safety procedures. Poor hand hygiene standards at the hospital has therefore had a number of consequences. Doctors' lack of confidence in the hospital's hygiene standards has led many to prescribe twice as many antibiotics than the norm, making treatments more costly for patients. The over-prescribing of antibiotics has also resulted in bacteria becoming multi-resistant in some instances. Usman Chatib Warsa, a microbiologist from the School of Medicine at the University of Indonesia believes that multi-resistant bacteria, such as Methicilline-Resistant *Staphylococcus Aureus* (MRSA) or Multiresistant *Pseudomonas Aeruginosa* has infected about 40% of patients treated in intensive care units in Indonesia in 2009. According to WHO data, 1.4mn hospital patients worldwide suffer healthcare associated infections at any given time.



Poor hand hygiene standards and the ensuing increased risk of such infections prompted the Indonesian Ministry of Health to launch a hand hygiene campaign in November 2009, targeting hospitals throughout the country. The Ministry, which has adopted the WHO's hand hygiene initiative, has targeted not only healthcare workers, but also visitors and patients, so as to institutionalise alcohol-based hand-cleaning. According to the WHO's 'First Global Patient Safety Challenge' Director, Didier Pittet, the hand hygiene campaign has already shown promising results. It is thought that 90% of hospitals that have adopted the campaign have demonstrated some improvements, as well as a reduction in the rates of infection among patients

Moreover, the lack of adequate primary care coverage means that hospitals are overcrowded, despite the rising costs of various treatments offered at such institutions, which have to be largely subsidised by the patients themselves. The situation has worsened as the result of a series of natural disasters – including the December 2004 tsunami – which have destroyed many hospitals and other healthcare facilities in a number of provinces. In addition, the number of those who cannot afford healthcare is rising, increasing the pressure on overall healthcare provision.

At present, free healthcare is provided for fewer than 20% of the population, through a public health insurance scheme covering government employees. In some villages, community self-help schemes are in operation, whereby participants pay into a joint fund that covers healthcare and pharmaceuticals at local hospital outpatient centres and clinics.

In an effort to address this issue, the Indonesian government announced in February that it is to implement its long-awaited National Social Security System (*Sistem Jaminan Sosial Nasional*; SJSN) Law of 2004 later this year. The policy, which forms part of President Susilo Bambang Yudhoyono's five-year plan, would ensure every citizen is insured through social or commercial health insurance. The SJSN aims to include all Indonesians in a system of pre-paid contributions and assistance spanning pensions, work injury, health insurance, old-age savings and death benefits. At present, some workers are covered by health and old-age programmes, but these lack scope and generally do not deliver quality services. To introduce the SJSN, the government must debate the legislation, ensure communication between various ministries, create new fiscal obligations for the state budget and strengthen operational infrastructure, such as information technology (IT) systems. By rationalising existing schemes under a single entity, **BMI** believes efficiencies will be realised, resulting in benefits for pharmaceutical companies operating in the South East Asian country.

The SJSN will become an 'umbrella' agency over the four existing social security companies – **PT Jamsostek**, **PT Askes**, **PT Asabri** and **PT Taspen**. The legal structure of these firms will be changed from *perseros* (for-profit entities responsible to their shareholders (i.e. the government)) into trust funds (not-for-profit entities managing the funds in the best interests of the participants). However, a proposal to consolidate the four companies into a single fund was rejected because of the potential for corruption. According to Hotbonar Sinaga, president of PT Jamsostek, it would be 'impossible' to entrust a

healthcare program that covers 230mn people to a sole provider. **BMI's** Country Risk team recently stated that corruption in Indonesia is still at high levels and presents a challenge to economic growth prospects.

Once the SJSN has been ratified, enrolment to social security schemes will be promoted. The initial focus will be on marginalised groups, such as the elderly, disabled, informal workers (such as those who do not pay tax) and the unemployed. It is estimated that universal membership will take approximately 25 years. Social security healthcare is a rapidly expanding market in Indonesia. Data extrapolated from the WHO reveals that expenditure in 2009 reached US\$1.87bn, or 22.0% of total government health spending. By 2014, the value of the social security healthcare market will have reached US\$11.09bn

Given that the social security law mandates the realisation of healthcare for all through taxes and contributions, the government is therefore obliged to insure the poor, orphans and the neglected elderly, while the rest of the population is expected to be insured privately or by their employers. It is expected that the Ministry of Health would rely on state-owned insurance companies and local administrations to extend the insurance coverage. So far, one such avenue has opened up through local administrations which sponsor *Jamkesda*, or healthcare schemes for citizens. Such schemes are financed by a particular region's budget as well as citizen contributions.

Findings by the WHO's National Health Account recorded that Indonesia's total spending on healthcare stood at 2.5% of the country's GDP in 2007 – a figure which was lower than Thailand, which had a contribution of 3.5% of GDP, and Malaysia which had 4.4% of GDP. While it is envisaged that the government's healthcare program will increase spending through a combination of a larger amount of funds being allocated to improve *Jamkesmas* (public health schemes), and through enhanced citizens' contributions, it should be noted that an increase in spending does not directly translate into an improvement in the quality of care provided.

While Chalik Masulili, Assistant to the Ministry of Health Financing and Community Empowerment has acknowledged that simply boosting spending might be futile if no measures were applied to controlling costs and the quality of care provided, he did offer assurances that as part of efforts to prevent unnecessary claims in *Jamkesmas*, the government has begun to implement a Diagnosed-Related Group (DRG) system, whereby a price-coded mechanism would automatically give hospitals standard treatment and the medicine necessary for a patient's care. The code, which entails six digits that represents the type of illness, severity and class of health provider, would replace the random payment system that has been practiced in the country for decades – a system which often resulted in substantial hospital bills and a meager quality of care. The purpose of the coding system is to automatically reject non-relevant medicines or treatments suggested by hospitals. It is thought that of the 900 hospitals that have tried out the system this year, 90% have succeeded in implementing it. Due to the inadequacies of the healthcare system, a growing number of Indonesians have sought to obtain medical treatment overseas. Figures released by the Indonesian Medical Association (IDI) suggest that every year, wealthy Indonesians spend

more than US\$1bn on their medical expenses abroad, with Singapore, Australia, Malaysia and the US cited as the main destinations for treatment. Overall however, Indonesians spend a total of US\$12bn per year on healthcare.

According to a report compiled by Frost and Sullivan, over the past three years, Indonesians have spent SGD800mn (US\$575.44mn) and MYR160mn (US\$47.46mn) in Singapore and Malaysia per year respectively. While Singapore has gained far more than Malaysia in terms of value, the latter has more recently gained ground in terms of growth, with the number of Indonesian patients visiting the country per year increasing steadily. The number of Indonesian medical tourists visiting Malaysia comprised about 70% of the country's total international patients; while those visiting Singapore for treatment amounted to about 65%.

In 2008, Malaysian hospitals treated 288,000 Indonesian patients, thus generating MYR182.16mn (US\$54.08mn) in revenue. This marked a significant increase from the 221,538 patients treated and MYR157.03mn (US\$46.60mn) revenue earned in 2007. In 2006, Malaysian hospitals treated 170,414 Indonesian patients, earning MYR135.37mn (US\$40.17mn) in revenue. In the case of Singapore, 226,200 Indonesian patients were treated locally in 2007, generating an income of SGD1.1bn (US\$791.23mn) that year. While the number of patients dropped from the 266,500 recorded in 2006, the revenue earned in 2007 was higher than the SGD850mn (US\$611.38mn) recorded in 2006.

According to Simranjit Singh, Associate Director of Healthcare for the Asia-Pacific Region at Frost and Sullivan, the primary reason for Indonesians seeking medical treatment abroad was the inability of the domestic healthcare sector to cater to the demands of the middle classes searching for a better service. However it is thought that several factors could boost the growth prospects of the healthcare sector in any country. The first is connectivity – given that hospitals should be located near to main roads, airports and other transportation hubs. The second is accreditation of doctors, nurses and the hospital's facilities so as to enable cross compatibility with the West, since patients can be from the Middle East, America or East Asia.

## Healthcare System Reform

The government is committed to the improvement of public health. The country is committed to a number of goals under its 'Healthy Indonesia 2010' programme:

- To initiate and lead a health orientation of the national development;
- To maintain and enhance individual, family, and public health along with improving the environment;
- To maintain and enhance quality, accessible and affordable health services; and,
- To promote public self-reliance in achieving government health.

The Poor Community Health Insurance (*Askeskin*) scheme was launched in January 2005, with other populist measures enacted subsequently. *Askeskin* is a programme directed at poor people, allowing them access to healthcare. However, in March 2008, the scheme was re-named *Jamkesmas*, or the Public Health Assurance Programme.

The current thrust of the health improvement plan is the 'Everything priced IDR1000 (US\$0.11)' campaign, which, according to the Workers Rights Consortium, allows patients to get a course of commonly prescribed medicines for what equates to a very affordable 0.5% of the average weekly wage (US\$20.50).

As part of the government programme, local drugmakers have recently been urged to participate in an ultra-cheap medicine programme promoted by the government to improve the quality of their products. In addition, domestic firms are encouraged to increase output and ultimately raise export figures to keep pace with the rapidly expanding capabilities of India and China. In return for co-operation, a possible tax-incentive for medicine manufacturers has been mooted.

However, government intervention in pricing may stifle outside investment, ultimately to the detriment of patients. Moreover, in July 2007 the government enacted the controversial Investment Law, which seeks to ring-fence protectionist measures for the local industry. Under the legislation, the 'negative list' of Indonesian companies for which foreign investment is partially or wholly restricted has been expanded significantly.

Despite such concerns, FDI is likely to continue growing at a relatively respectable pace, assisting Indonesia's economic development. During the first eight months of 2007, the chemical and

pharmaceutical industry received FDI worth US\$6.9bn, making it the second most popular sector behind paper and printing. However, a cut in taxes would go further towards improving the situation.

However, change is underway despite the numerous challenges that lie ahead. In September 2009, the government of Indonesia announced its intention to set in motion a number of healthcare reforms. The recently re-elected President, Susilo Bambang Yudhoyono stressed his commitment to improving the provision of medical services during his second five-year term in office. Given Yudhoyono's strong political position, **BMI** believes that fundamental changes can be made. However, significant risks also exist, such as growing radical Islamism that may restrict investment from the foreign commercial sector.

At present, healthcare spending accounts for just 2.59% of GDP, which is low by both regional and global standards. The country's distribution of medical services is inequitable, with a notable bias against rural areas and outlying islands. Nevertheless, **BMI** expects Indonesia's spending on health to increase from US\$12.65bn in 2008 to US\$33.09bn in 2014, equating to a compound annual growth rate of 18.59%.

To improve the health of Indonesians, Yudhoyono plans to increase the government budget for hospitals, doctors and nurses, medical devices and pharmaceuticals. Spending will also be increased on preventative measures in order to tackle high-burden infectious diseases such as dengue fever, malaria and HIV/AIDS. Better training of healthcare workers has also been cited as a priority.

## International Healthcare Collaborations

In October 2005, Indonesia and Vietnam agreed to increase bilateral co-operation in areas relating to healthcare services, drug production and the fight against infectious disease – through the production of new vaccines for epidemics threatening ASEAN members. In the field of healthcare services in particular, both countries pledged to promote technology transfer schemes as well as to encourage the exchange of healthcare personnel between the two nations.

In September 2007, the WHO reiterated its encouragement of public-private partnerships (PPPs), which would target neglected diseases in the Western Pacific region. Big pharma on the whole has ignored these conditions and concentrated on chronic diseases, such as diabetes and heart disease, which are common in the affluent Western world. According to a WHO study, of the 1,400 new drugs introduced between 1975 and 1999, only 13 were for tropical or neglected diseases – despite these conditions accounting for half of the disease burden in Asia, Latin America, Africa and the Middle East.

PPPs in the field of healthcare are a relatively new phenomenon and follow similar schemes in the transport sector, which pioneered the concept to complete massive projects such as highway building. The **Global Alliance for Vaccines and Immunization** (GAVI) is perhaps the best known and the majority of its operations – approximately US\$750mn in value – are funded by Bill Gates, the chairman of software

company **Microsoft**. Other examples include the **Global Fund to Fight AIDS, Tuberculosis & Malaria**, the **TB Alliance** and the **Drugs for Neglected Diseases Initiative**.

In April 2009, Singapore-based drug development company **Innogene Kalbiotech Private Ltd** announced that it had signed a Memorandum of Understanding (MoU) with a Malaysian clinical research organization, **Info Kinetics Sdn Bhd** to provide accredited Bioavailability and Bioequivalence (BA/BE) studies in Indonesia. Innogene will act on behalf of the biopharmaceutical unit of domestic pharmaceutical firm **PT Kalbe Farma**.

Through the signing of the MoU, both companies have entered into a joint venture agreement to establish PT Pharma Kinetics, a world-class BA/BE clinical research centre designed to serve both the domestic, as well as ASEAN clinical trials markets. Under the terms of the agreement, PT Pharma Kinetics will be based in a hospital in Jakarta, Indonesia. The company's operations will be supported by PT Pharma Metric Labs, an Indonesian-based BA/BE research organisation set up by Innogene in 2005. Both companies have previously worked together on Innogene's pioneering product, *TheraCiM* (nintozumab), an anti-cancer drug which has achieved successful commercialisation in parts of Asia.

In the long term, PT Pharma Kinetics hopes that the results obtained from its international Bioequivalence studies program can assist local generic drug manufacturers to register and export their products to developed pharmaceutical markets within Australia and Europe. Although a number of BA/BE centres already exist within the ASEAN region, only a handful are fully ISO/IEC-accredited and located within a hospital environment. This collaboration therefore aims to fill the gap that exists in both the Indonesian and ASEAN markets.

Given that Innogene's parent company Kalbe Farma owns the **Mitra Keluarga Hospital** chain in Indonesia, both companies believe that the new facility could tap in to the group's resources to become a leading centre for BA/BE studies in the region. Info Kinetics currently operates dedicated early clinical research wards in the **Pantai Hospital** and the **Gleneagles Medical Centre** in Penang, Malaysia. The company also established Southeast Asia's first and only GLP accredited laboratory at the **Universiti Sains Malaysia**, which was accredited by the Organisation for Economic Co-operation and Development (OECD).

## Pharmaceutical Retail Sector

There are approximately 10,100 pharmacies in Indonesia, equating to 4.3 outlets per 100,000 population. While this is fairly respectable for a developing country, only 30% of the 27,000 pharmacists have competency certification, with the majority active in Java. BMI believes that this may result in a higher than expected dispensing error rate. This in turn would have a negative impact on the burden of disease in the most populous country in South East Asia.

It must be noted however that the Pharmacist Professional Competence Certification (SKPA) has only been available in the country since 2006. Another issue for the sector is the lack of outlets holding licences. According to the Association of Indonesian Pharmacy Graduates, only 20% of pharmacies in Indonesia have licences. The majority of unlicensed outlets are located in under-developed provinces, such as Kalimantan and Papua, where there are no pharmacy colleges. Additionally, many prescription-only medicines can be purchased as OTCs.

The Indonesian medicine retail sector received a major boost in June 2007 when the government launched a programme to increase the availability of cheap, locally made versions of patented pharmaceuticals. Under the Apotek Rakyat (People's Pharmacy) scheme, restrictions on dispensing drugs have been loosened and a network of small pharmacy outlets is being encouraged.

The Apotek Rakyat programme is a bold move by the Indonesian government. At least one qualified pharmacist must be present in each outlet. Bulk purchases by consumers are outlawed and there are restrictions on the type of medicines that can be sold. For example, narcotics – such as the semi-synthetic opioid derivative Vicodin (hydrocodone) – and psychotropics are banned from kiosks. Most importantly, the dispensing of domestically produced generics will be encouraged and medicine compounding prohibited.

## Research and Development

Indigenous R&D activities in Indonesia are limited, due to the scarcity of financial resources of most local firms, but also due to a substandard IP environment that has allowed for the proliferation of counterfeit drug activities.

Nevertheless, some foreign companies are looking to expand into the country. In February 2007, US company PharmaTrials International, a subsidiary of New Life Scientific, revealed plans to expand its presence to Indonesia and China. The Asian region provides advantages in terms of easy access to specific disease and treatment-naïve populations, which is illustrated by the growing interest in conducting clinical trials in the region.

Moreover, in January 2007, the Singapore-based **Novartis Institute for Tropical Diseases** (NITD) created a new clinical research initiative in Indonesia, which will focus on R&D for treatments for tuberculosis, dengue fever and malaria. The NITD is to collaborate with the Eijkman Institute in Jakarta and the Hasanuddin University Clinical Research Institute in Makassar, with a view to recruiting local experts and gaining direct access to hospitals and patients suffering from these diseases in a 'real-life' context.

Indonesia has taken a significant step in eliminating malaria from the archipelago. A government agency successfully harvested a crop of sweet wormwood (*Artemisia annua*), which contains the active

ingredient in the most effective malaria drug available. Artemisinin is used in combination with amodiaquine, lumefantrine or piperaquine in the treatment of malaria. BMI welcomes the development as it will reduce the cost of obtaining the medicine, enabling more patients to be treated. It also endorses the state's efforts to promote local manufacture of pharmaceuticals.

Sweet wormwood is native to China and Vietnam, but is also grown in East Africa. To reduce reliance on foreign supplies, Indonesia's Health Ministry's Agency for Research in Medicinal Plants and Traditional Medicines started growing the herb in 2006. A batch of seeds is now ready for distribution, but local farmers still need convincing that it is more beneficial to grow sweet wormwood than vegetables. Indonesia hopes to produce its own artemisinin by the end of 2010.

About 45% of Indonesia's 230mn population live in areas where malaria is endemic. According to the *World Malaria Report 2008*, more than 2.5mn Indonesians were infected with the disease in 2006, the latest figures available, with a known death toll of 3,480. According to BMI's *BoDD*, a total of 0.998 DALYs were lost to malaria in Indonesia per 1,000 population during 2008, falling below the regional average. However, it should be noted that if the developed states of Japan, Singapore, Australia and Hong Kong were excluded from the calculation, Indonesia would have a higher than average relative burden.

## Herbal Medicines

Traditional medicines are well represented in Indonesia, partly due to culture and partly due to the fact that the majority of the population need to pay for their own medical products. Indonesia has a particularly buoyant market for herbal medicines, which are locally known as *jamu*. However, the local authorities have indicated their intention to tighten regulations, which would have a disastrous effect on the domestic industry as most producers do not follow current guidelines and could be forced to close if higher standards are implemented. While challenging in the short term, the development holds a strong long-term potential, particularly in relation to the nascent export sector.

Indonesia has 1,243 *jamu* producers and over 10% are large-scale operations. The rest are small and medium-sized firms, operating predominantly in East and Central Java. However, only 10 companies make *jamu* that adheres to BPOM's standards. Strict enforcement of regulations will result in consolidation among firms that cannot upgrade output. Another threat is the mainstream pharmaceutical companies. One drugmaker recently introduced a semi-herbal medicine to treat *masuk angin*, a local term for wind-based illnesses.

Sales of *jamu* are forecast to decline by 17.6% to IDR7trn (US\$587mn) in 2009, according to the Indonesian Herbal and Traditional Medicines Entrepreneurs Associations (GP Jamu). The main reason for this is the tendency for Chinese manufacturers to dump their products in Indonesia.



**Nyonya Meneer** and **SidoMuncul** are the leading *jamu* manufacturers in Indonesia. Importantly, both firms produce 'quality' preparations, enabling them to sell abroad. Leading export destinations include Malaysia, Singapore, the Philippines, Taiwan, Saudi Arabia, the US and the Netherlands. The value of exports was a modest US\$4mn in 2007, but GP Jamu expected this figure to double in 2008, in part due to an international symposium on the herbaceous plant *temulawak* (*Curcuma xanthorrhiza*).

## Medical Devices

Medical devices are regulated in Indonesia by the government-controlled NADFC/BPOM. In 1991, to protect healthcare professionals and patients from unsafe equipment, the agency drafted Regulation No. 1477/C/SK/IV/91 – Directives for Registration of Medical Devices, Cosmetics and Household Health Supplies. If there are any changes to the components, materials, labels, packaging or any other fundamental part of the product, the applicant must register these changes by filling out the data changes application form. The director general of NADFC/BPOM can cancel any registration if the device proves to be unsafe, is of low quality or differs from the approved label. Locally-produced devices must be registered by domestic firms, while imported goods must be processed by Indonesian distributors under authorisation from the foreign manufacturer and the local authorities. Applications are evaluated according to Regulation No. 140/Menkes/Per/III/91, and a decision can be expected within three months.

Compared to developed countries, Indonesia's disease burden is disproportionately represented by infectious conditions, such as HIV/AIDS and tuberculosis. Accordingly, there is significant opportunity for manufacturers of diagnostic kits for communicable diseases. In fact, in July 2009, China-based **Hard to Treat Diseases** was poised to ship 250,000 doses of Mevac-ACYW, meningococcal polysaccharide vaccine, to Indonesia. The order was the second tender won in the last year, with the company already having exported 70,000 doses to Indonesia in late 2008.

Locally made devices account for just 15% of the sector's total value and are mainly basic goods such as crutches, wheelchairs and disposables. Most of the products used in the country are imported, with the US (US\$31.8mn), Germany (US\$29.5mn) and Japan (US\$22.1mn) the leading sources in 2006. Much like pharmaceuticals, equipment that is made abroad in developed countries is perceived as being of higher quality and therefore can demand a premium price. Among US manufacturers, **Johnson & Johnson** (J&J), **GE Healthcare** and **Becton Dickinson** are market leaders. Foreign goods are subject to a 0-5% import levy and a 10% value-added tax.

# Industry Forecast Scenario

## Overall Market Forecast

**BMI's** Drug Expenditure Model shows that Indonesia's pharmaceutical market will reach a value of IDR81.03bn (US\$10.13bn) by 2019. The main drivers are: a booming economy; high inflation; significant population growth; and increased government spending. Many opportunities exist for foreign drugmakers, but barriers to entry include a protectionist business environment, a high prevalence of counterfeit medicines and an opaque pricing and reimbursement regime.

In 2008, sales of pharmaceuticals increased by 9.05% to reach IDR26.89bn

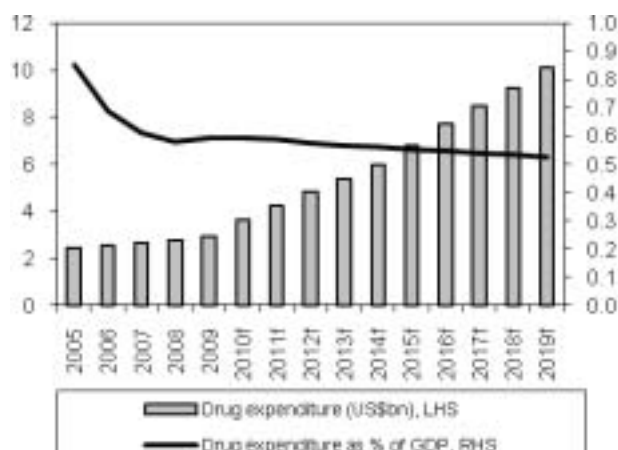
(US\$2.92bn), making Indonesia one of the fastest growing markets in the Asia. However, mainly as a result of reduced demand for the country's exports during the global economic downturn, medicine sales are projected to expand by just 2.32% in 2009. Healthy growth will return the following year and we are forecasting CAGRs in local currency terms of 10.89% and 10.35% for 2009-14 and 2014-19, respectively.

Increased fiscal expenditure and growing government involvement in the pharmaceuticals sector will benefit drugmakers. In 2007, Indonesia spent 2.48% of GDP on health, which is low by regional and global standards. Of this US\$10.73bn, just over half was spent by the state. By 2014, **BMI** expects government and overall healthcare spending to reach US\$22.38bn and US\$33.43bn, respectively.

A strengthening rupiah will benefit foreign drugmakers. The IDR:US\$ exchange rate is forecast to decrease from 9,685:1 in 2008 to 8,375:1 in 2014, and to 7,875:1 in 2019. While the pharmaceutical market will post a five-year CAGR of 10.89% in local currency terms, the corresponding figure for US dollars is 15.35%.

According to **BMI's** Country Risk team, Indonesia's economy continued to outperform strongly in Q409, registering real GDP growth of 5.4% y-o-y and taking full-year growth to a robust 4.5%. **BMI** remains

**Pharmaceutical Market Forecast**  
2005-2019



*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI. For data, see Forecast Tables section below.*

bullish about Indonesia's growth prospects over the coming year, projecting real GDP growth to reach 5.2% in 2010, prior to increasing to 5.5% in 2011.

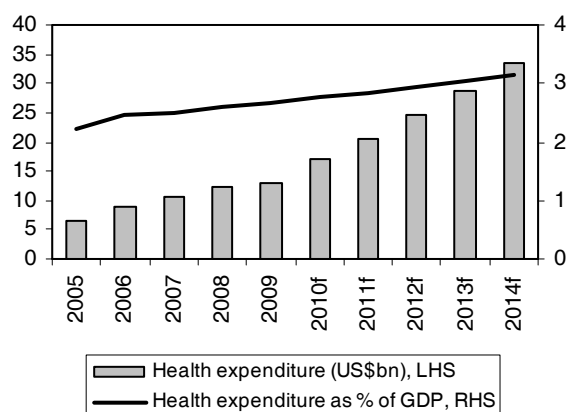
Key drivers of future market growth are related to Indonesia's demographics; average life expectancy is rising, creating an increase in degenerative diseases and so boosting demand for Western-style drugs. On the other hand, the country is still suffering problems due to communicable diseases (most notably dengue fever and malaria), a situation made worse by restricted access to pharmaceuticals. This has also led to the growth in the use and popularity of herbal medicines, which are expected to pose a threat to OTCs over the coming years.

In addition, despite having one of the largest drug markets in the region, the Indonesian government continues to spend less on health than any of its neighbouring countries, forcing patients to foot their own drugs bill. Consequently, prescription drugs will be vulnerable to economic downturns, as well as to the tide of counterfeit drugs allowed by the lax IP regime and the low purchasing power of the population.

## Key Growth Factors – Industry

The government's priorities include restructuring regulatory policy and encouraging FDI, with plans to cut licence approval times for producing or wholesale trading from 150 days to 30. However, much of the restructuring currently remains on paper and continued uncertainty should delay any marked increase in foreign investment in the sector in the short term. In addition, the recently enacted controversial Investment Law will serve to restrict FDI. Overall, there is unlikely to be any significant improvement to the regulatory regime until ASEAN regional harmonisation takes place fully.

### Healthcare Expenditure Forecast 2005-2014



*f = forecast. Source: World Health Organization (WHO), BMI. For data, see Forecast Tables section below.*

Nevertheless, local drugmakers should begin to feel the benefits of recent government reductions on tariffs for raw materials. Import tariffs on 11,171 products across a wide range of industry groups – including pharmaceuticals – have been lowered as the country endeavours to comply with global FTAs. The new maximum duty will be 5%, with the process completed by 2010.

Reaction has been mixed. Some local manufacturers are pleased that they will be able to source cheaper raw materials, although others are concerned that the domestic market is being increasingly exposed to competition. One protectionist measure that has been suggested would be to maintain the improved tariff structure for APIs, but continue to protect the local industry against the import of finished products.

The government has announced that it is to offer tax incentives for both new and existing investors in a number of industry sectors. The facilities will be offered to firms building new factories or expanding businesses in the chemicals, petrochemicals and pharmaceuticals industries. The authorities are confident that this will further encourage foreign investment, with other plans aiming to attract foreign capital including the proposal to remove the pharmaceutical industry from the 'negative investment' list.

## Key Growth Factors – Macroeconomic

### **Approaching Pre-crisis Levels of Growth**

***BMI View:** We remain bullish on Indonesia's growth prospects over the coming year, projecting real GDP growth to reach 5.2% in 2010, before accelerating to 5.5% in 2011. However, we note that the political situation has worsened following the implication of Vice-President Boediono and Finance Minister Sri Mulyani Indrawati in the Bank Century bailout scandal.*

Recent economic data released across the globe has been generally encouraging and many countries in Asia maintained the V-shaped rebound through Q409 as external demand remain robust. As such, our global growth forecast now stands at 3.0% for 2010, representing a decent recovery for the global economy from an estimated -1.8% outturn in 2009. Notably, we expect emerging Asia to outperform the other regions, projecting real GDP growth to reach 7.2% in 2010, compared with just 1.8% for the developed states. Although trade-dependent economies are likely to benefit inordinately from resurgent external demand, the sustainability of the recovery beyond the next two quarters is still in question. As such, while export-driven economies are likely to show a larger jump in real GDP growth with respect to 2009, domestic demand-driven economies such as India and Indonesia have a more stable platform for growth.

Indonesia's real GDP growth came in at a robust 5.4% y-o-y in Q409, taking full -year 2009 GDP growth to 4.5% (slightly above our forecast of 4.3%). We remain bullish over Indonesia's growth prospects over the coming year, projecting real GDP growth to reach 5.2% in 2010, before accelerating to 5.5% in 2011. Underpinning this sanguine outlook is our expectations that the country's large domestic economy will continue to perform well. Indeed, Indonesia - with less dependence on exports - is also relatively insulated against a slowdown in the US (from 2.8% in 2010 to 1.8% in 2011) or China (from 9.0% in 2010 to 7.7% in 2011), which we expect to happen in late H210.

### **High Private Consumption Growth Maintained**

Private consumption growth held at 4.0% y-o-y in Q409, contributing the lion's share of 2.4 percentage points (pp) to headline growth. Going forward, we expect a robust figure from this component of GDP, forecasting private consumption growth to reach 5.5% in 2010. We see two key reasons supporting our view. Firstly, we believe that the BI will keep the benchmark rate relatively low for the next two years (envisioning only a 125bps rate hike by end-2011), supporting more uptake of household debt. Secondly, the projected increase in investment in the coming quarters should provide a boost to real wages, thereby bolstering private consumption.

More signs have also been appearing in recent months that support our upbeat view. Indeed, Indonesia's unemployment rate (released bi-annually) actually fell from 8.14% in March 2009 to 7.87% in August 2009, despite the downturn. We expect the unemployment rate to further decline to 7.6% by end-10,

providing considerable support to household spending. In addition, consumption will be fuelled by further rupiah strength (we currently project the unit to appreciate to IDR8,900/US\$ by end-10). Moreover, consumer confidence is still holding up well, judging from the robust car sales registered towards the end of 2009, and we expect this to continue over the medium term.

### **Investment Picking Up**

Gross fixed capital formation (GFCF) growth accelerated for a second consecutive quarter, rising by 4.2% y-o-y in Q409, contributing 1.0pp to headline growth. Although the figure is still far below the average 10.1% growth (a figure skewed to the upside given the global boom of the time period) seen in 2007-2008, the trend has been encouraging and we currently project GFCF growth to reach 5.0% in 2010. Given the strong performance of the economy, businesses are likely to increase investment in the coming quarters. Indeed, in the latest Business Survey conducted by Bank Indonesia (Q309), there was increased optimism regarding the business situation. Moreover capacity utilization is already at 74.20% in Q409, close pre-crisis levels, indicating that businesses will have to invest to cope with increasing demand. Business lending will also be facilitated by our expectation that Bank Indonesia will keep the BI rate low and embark on more efforts to encourage further lending by commercial banks

### **External Sector Holding Up**

In a further sign that global trade flows are normalising, export and import growth (referring to both goods and services) finally turned positive on a y-o-y basis after three consecutive quarters in negative territory, with export recovery vastly outpacing import growth. However, we believe that this trend is poised for a reversal given our outlook that Indonesia's domestic demand will fuel stronger import growth. Moreover, with the Asean-China Free Trade Agreement (FTA) in effect since the beginning of this year, there is a likelihood that import of chinese goods may surge. That said, we acknowledge that Indonesian exports will also benefit from the FTA and it is premature to assess the net impact on Indonesia's trade balance until further data is available. Currently, we expect export growth to reach 8.5% and import growth to reach 9.9% in 2010.

### **Optimism Tempered By Clouding Of Political Situation**

Despite our bullishness on the Indonesian economy, we note that the domestic political situation has become decidedly cloudier. While we had been optimistic following the strong mandate garnered by President Susilo Bambang Yudhoyono during the presidential elections in 2009, the scandal involving the bailout of Bank Century poses a serious overhang. In the worst case scenario, Vice-President Boediono and Finance Minister Sri Mulyani Indrawati (both of whom are crucial towards further economic reforms) would stand to lose their positions.

Table: Indonesia – Economic Activity

	2007	2008e	2009e	2010f	2011f	2012f	2013f	2014f
Nominal GDP, IDRbn <sup>1</sup>	3,955,630	4,627,989	5,080,866	5,623,103	6,303,476	7,081,861	7,922,408	8,804,755
Nominal GDP, US\$bn <sup>1</sup>	431.7	474.3	490.4	614.5	720.4	828.3	932.0	1,035.9
Real GDP growth, % change y-o-y <sup>1</sup>	6.3	6.1	4.5	5.2	5.5	5.4	5.2	5.0
GDP per capita, US\$ <sup>1</sup>	1,864	2,023	2,067	2,561	2,968	3,375	3,756	4,131
Population, mn <sup>1</sup>	231.6	234.5	237.3	240.0	242.8	245.4	248.1	250.7
Industrial production index, % y-o-y, ave <sup>1</sup>	2.0	3.1	1.3	4.0	4.5	5.8	6.0	5.8
Unemployment, % of labour force, eop <sup>1</sup>	9.1	8.4	7.9	7.6	7.2	7.0	7.0	7.0

Notes: <sup>f</sup> BMI forecasts. Sources: <sup>1</sup> BMI/IMF.

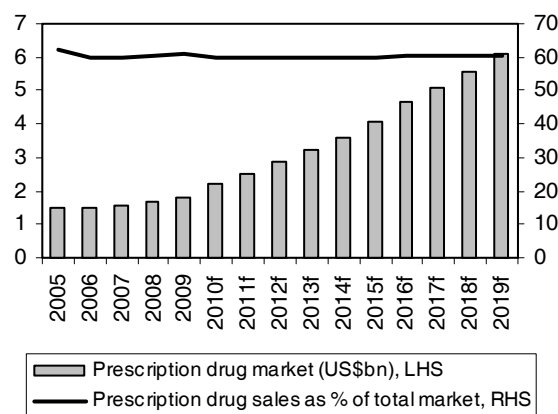
## Prescription Drug Market Forecast

Prescription drugs accounted for about 60.5% of total drug market expenditure in 2008, with the figure likely to fluctuate marginally through to 2019. Therefore, prescription medicines will continue to dominate in terms of market shares, even though the distinction between non-prescription and prescription segments remains blurred.

Foreign producers will continue to supply the hi-tech end of the market through imports, although the considerable amount of counterfeit drugs on the market distorts the real figures.

Additionally, the requirement that foreign companies must now have local production facility threatens to remove some of prescription drugs from the market..

**Prescription Drug Market Forecast**  
2005-2019



*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI. For data, see Forecast Tables section below.*

Following the receipt of confirmed 2009 data, **BMI** has revised upwards its forecast for Indonesia's pharmaceutical market. According to local drug manufacturer **PT Kalbe Farma**, total sales of prescription drugs in the South East Asian country increased by a better than expected 13.2% last year to reach IDR18,407bn (US\$1.78bn). By 2019, prescription sales are likely to reach almost IDR48,922bn (US\$6.12bn), up from IDR18,406bn (US\$1.78bn) in 2008. In local currency terms, CAGRs of 8.46% and 9.59% for 2009-14 and 2014-19, are forecast respectively. These will be driven by rising demand and growing population but hampered by the government's programmes for the reduction of pharmaceutical expenditure, including price cuts. However, many of the leading branded drugs will be exempt from the cuts, which will mainly focus on generic drugs on the National Essential Drugs List. Antibiotics will remain one of the most dominant segments, although some moves to rationalise their prescription can be expected

Owing to its level of economic development, the most common therapeutic areas in terms of sales are cardiovascular drugs, which posted 2008 sales of US\$326.5mn; followed by nervous system medications which stood at US\$232.9mn; and alimentary tract treatments, which stood at US\$192.6mn. **BMI** expects sales of these therapeutic areas to continue to dominate over the next five years

Other drivers of growth include the fact that hospitals remain the primary source of healthcare. Moreover, foreign entities may start investing more in local drugmakers and drugmaking industry, if the proposed



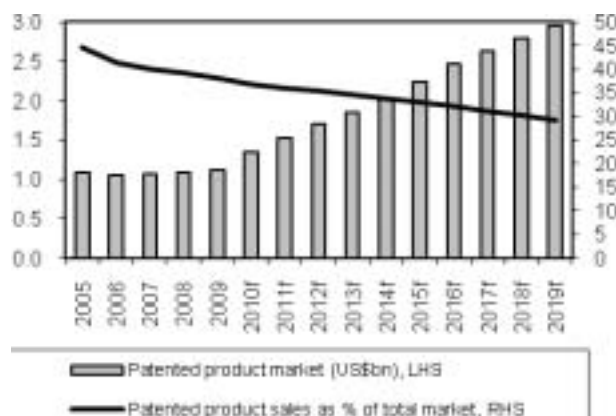
removal of the pharmaceutical industry from the 'negative investment' list is carried out. On the other hand, local drugmakers should benefit from the cuts on tax levied on API imports.

## Patented Product Market Forecast

The vast majority of patented drugs in the country will remain marketed by foreign drug firms, which will benefit from rising demand and the gradual improvement of regulatory and other standards. Higher-income Indonesians' preference for premium-patented products manufactured by international pharmaceutical firms will remain one of the key drivers.

Marketing efforts by foreign companies will promote brand awareness, especially in the private sector. The gap potentially made by the removal of certain products from the market (following the enforcement of the regulations mandating foreign companies to have local manufacturing facilities) is likely to be filled by their competitors.

### Patented Product Market Forecast 2005-2019



*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI. For data, see Forecast Tables section below.*

The Food and Drug Monitoring Agency (BPOM) has stated that the continuation of a fake drugs trade has again been discovered after a thorough three-month investigation in 2009 on towns across the islands of Java and Sumatra. The counterfeit products included antibiotics, contraceptive injection drugs, antifungal agents and antihypertensive medications. Patented drugs are far more frequently targeted by counterfeiters than generic drugs as they offer higher margins. Nevertheless, we forecast that the value of patented drugs will increase from IDR10.533bn (US\$1.08bn) in 2008 to IDR23.626bn (US\$2.95bn) in 2019. In local currency terms, the sector will post CAGRs of 8.32% and 7.43% for 2009-14 and 2014-19, respectively.

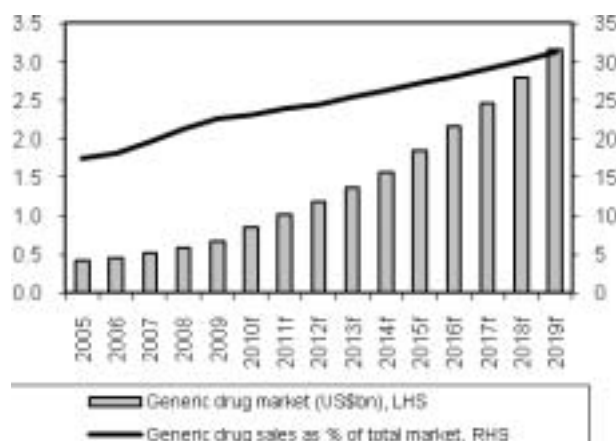
Meanwhile, there are continuing calls in the country to cap the price of branded drugs, which will likely reach a crescendo if the economic downturn is prolonged. The IPMG insists that drug companies are not to blame as they are only responsible for ex-factory prices, not for wholesale and retail margins, which the group says are comparable with other ASEAN countries. The body claims that over the past decade IPMG members have ploughed US\$900mn into the development of new drugs in Indonesia. The IPMG also reiterates the fear – often cited by multinationals facing such reductions – that price controls inevitably lead to the unavailability of medicines for the general public and suggests that the best way forward for the country would be the introduction of a national health insurance system.

## Generic Drug Market Forecast

The generic drug market is expected to expand at a faster rate than that of patented drugs, in both value and volume terms, with the products' low cost and affordability for the public sector driving growth as well as support by government policies. The imminent expiry of patents on a number of major drugs is expected to facilitate low-cost manufacturing, further boosting the consumption of generics.

**BMI** forecasts that generic drug sales in Indonesia should increase from IDR5,727bn (US\$587mn) in 2008 to IDR25,296bn (US\$3.16bn) in 2019, posting CAGRs in local currency terms of 18.59% and 16.01% for 2009-14 and 2014-19, respectively.

**Generic Drug Market Forecast**  
2005-2013



*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI. For data, see Forecast Tables section below.*

The government is active in promoting generics medicines, the quality and price of which are controlled by the Ministry of Health. The use of generics is encouraged through public campaigns, while public healthcare institutions are obliged to use generics. Generics substitution is allowed, subject to the patient's approval.

Meanwhile, in a move that has angered US pharmaceutical association PhRMA, the Indonesian authorities have recently implemented new legislation requiring that any branded pharmaceutical product display its generic name directly beneath the trade name. The changes are seen as disadvantaging original products, as well as violating international trademark laws.

The above factors, combined with the low purchasing power of the majority of the population, have created ripe conditions for the enhanced uptake of low-priced generic pharmaceuticals. The generic drug sector should grow steadily as the government continues to promote the low-cost sector, with the percentage of generic drugs will rise to over 25% of the drug market in value terms by the end of the forecast period, although the push by multinationals for the introduction of bioequivalence legislation is likely to drive some generic products out of the market.

Additionally, the Ministry of Health is planning to reduce the prices of selected generic pharmaceuticals by up to 30% – as part of its strategy of improving access to basic drugs and medical care which will

impact market growth. The move comes amid claims that prices for some drugs are higher than in neighbouring Asian countries. The Ministry of Health has been looking to reduce the price of generics since May 2006, when it issued a decree on the topic.

However, according to reports in the Jakarta Post in February 2009, local industry sources doubt the quality of generic drugs in Indonesia. There are even allegations that some pharmaceutical companies have been dishonest in their claims about generic drugs, which are often manufactured with lower-quality ingredients than patented drugs. Community health experts also allege that public companies distort data for procurement and quality control documents, resulting in lower-quality drugs, while lower manufacturing standards in the industry results has a similar effect.

## OTC Medicine Market Forecast

The OTC market is expected to increase at a steady pace over the next 10 years, growing from IDR10,628bn (US\$1.09bn) in 2008 to an estimated IDR32,103bn (US\$4.01bn) in 2019. In local currency terms, the sector will post CAGRs of 11.45% and 10.48% for 2009-14 and 2014-19, respectively.

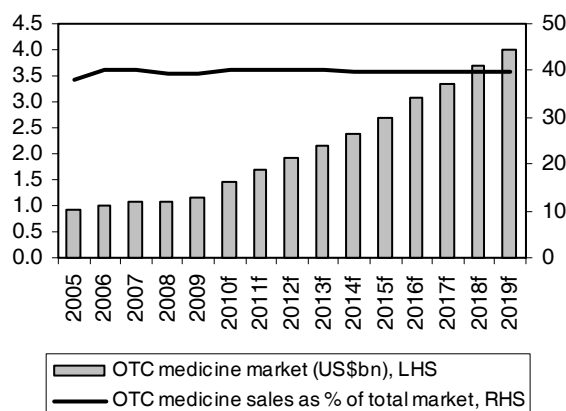
The relatively low cost and easy availability of OTC medicines will be the key growth-drivers as the sector increases its market share at the expense of the hospital-sourced drug market. The growing number of new communicable diseases will further stimulate the OTC market over the coming years, as patients seek to prevent contracting infection by any means possible.

Similarly, a difficult financial situation will preclude many from visiting doctors, instead driving them to turn to self-medication. Such factors are also encouraging the sales of herbal medicines. The lack of health insurance in the country is having a similar impact, as many patients cannot afford to fill their prescriptions and are forced to rely on low-cost consumer health products. Environmental factors such as severe air pollution in urban areas and contamination of water supplies are causing deterioration in health across the country, which should again help drive sales of OTCs as consumers attempt to manage their ailments.

OTC switches are determined by the NADFC, with company requests not allowed. Switches are approved depending on the product's ease of administration, proven safety and efficacy, no contra indications for children, the elderly and pregnant women, and for common and mild conditions, the treatment of which requires little professional supervision. Recent switches include antifungals tioconazole and terbinafine, and antirheumatic diclofenac.

By the end of the forecast period, OTCs are likely to gain percentage shares over prescription medicines in terms of market segmentation, although the distinction is at times difficult to make due to lax enforcement. Local drug companies will continue to control about 75% of OTC medicines sold in the country, with multinationals responsible for the remainder. Meanwhile, Indonesian consumers are

**OTC Medicine Market Forecast**  
2005-2019



*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI. For data, see Forecast Tables section below.*

showing a growing preference for herbal medicines, encouraged by government support in this area that has boosted sales for local producer **Sido Munucul**.

A sharp increase in the demand for 'preventative' and other OTC medications in recent years has contributed to the increased share of OTC drugs in the country's pharmaceutical sector. With 2008 sales of approximately US\$361.4mn, we expect that products comprising 'other OTC' sales to continue their dominance of the OTC sector through to 2019. A strong performance was also posted by vitamins and minerals as well as cough and cold remedies, which posted 2008 sales of US\$240.1mn and US\$221.2mn respectively. **BMI** expects sales of cough and cold medicines to continue their robust performance given the prevalence and the impact of avian and – more recently – swine flu.

## Medical Device Market Forecast

Indonesia's medical device market is characterised by imports, double-digit growth and an unmet need for affordable high-end offerings. Because of these attributes, **BMI** believes that medical equipment producers based in developed states should target the South East Asian country over the medium term. Frequent natural disasters are resulting in increased demand for surgical equipment, such as bandages, needles and sutures, although most of the demand for low-tech products is met by domestic suppliers.

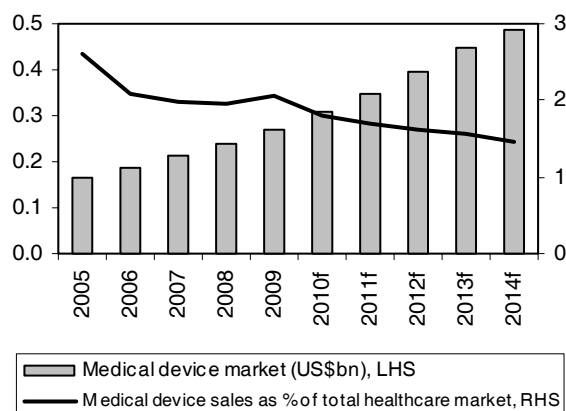
Extrapolating data from the US

Commercial Service, we estimate that the value of the sector reached IDR2.338bn (US\$240mn) by the end of 2008. Expansion of the medical device market will outpace that of the pharmaceutical sector, and a CAGR of 8.08% in local currency is projected through to 2014, when sales are expected to reach US\$488mn.

The main driver of the medical device market is a desire – both by individuals and the state – to spend an increasing proportion of GDP on healthcare, which is currently less than 3% according to the WHO. Decentralisation of power to regional governments is also resulting in the upgrade of hospitals and the formation of clinics that specifically serve those on low incomes.

However, a key restraint on growth is the emergence of medical tourism hubs in neighbouring Singapore, Malaysia and Thailand. Around 1mn Indonesians travel abroad for medical treatment each year, spending more than US\$1bn on medical tourism. Indonesians account for approximately 70% of international patients in Malaysia, and 65% of those in Singapore. In 2008, Malaysian hospitals treated 288,000 patients from Indonesia.

**Medical Device Market Forecast**  
2005-2014

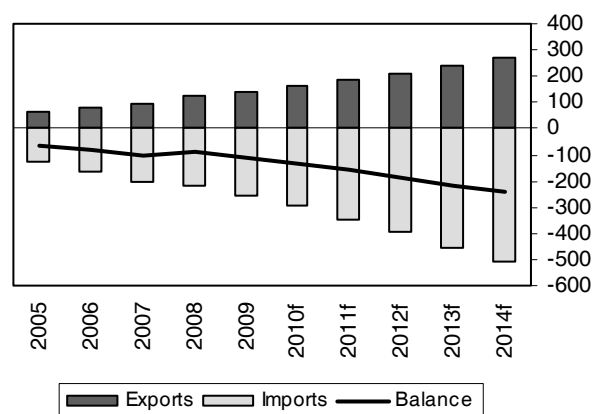


*f = forecast. Source: United Nations Comtrade Database, DESA/UNSD, BMI. Note: HS2002 - 3004 classification. For data, see Forecast Tables section below.*

## Pharmaceutical Trade Forecast

Indonesian pharmaceutical imports were valued at an estimated US\$215.9mn in 2008, with most foreign companies reaching the market through imported products. Additionally, some 90% of the 1,300 raw materials used to manufacture drugs in Indonesia are imported. Raw material prices are a problem due to weakening of the rupiah against the US dollar. In order to secure a low cost supply of APIs, Kimia Farma and Indofarma signed a contract with a Chinese active API supplier to provide bulk antibiotics.

**Pharmaceutical Trade Forecast (US\$mn)**  
2005-2014



*f = forecast. Source: United Nations Comtrade Database, DESA/UNSD, BMI. Note: HS2002 - 3004 classification. For data, see Forecast Tables section below.*

Indian drugmakers are also keen to expand in the Indonesian market, where they are already present through products entering as re-exports from Singapore. The majority of Indian exports to the country are for essential APIs, on which Indonesia is almost wholly reliant. However, the prevalence of Chinese nationals in Indonesia means that the country has greater business and economic links with China. This means that Chinese generic producers are, in the longer term, better positioned to capitalise on a demand for low-cost generic inputs in the country.

In a bid to offset high local-drug prices, the Indonesian government is also encouraging the import of low-cost pharmaceutical products from Bangladesh. Drugs from Bangladesh are 40-50% cheaper than similar products from Indonesia. The authorities have been attempting to offer cheaper drugs to the public for a number of years through imports, but there have been complaints over quality. This is not expected to be an issue in the future, as Indonesia will be importing branded rather than generic drugs from Bangladesh. The move is a result of pledges by the D-8 – Indonesia, Bangladesh, Nigeria, Iran, Malaysia, Pakistan, Egypt and Turkey – to reduce tariffs on a number of products from 25% to 10%.

Meanwhile, the value of Indonesia's US\$255mn pharmaceutical export sector is set to grow in light of the formation of a joint venture that will test medicines for quality – a vital requirement for purchasers in developed markets. Indonesian PT Pharma Kinetics will test medicines for bioavailability – the amount of drug that reaches the bloodstream – and bioequivalence, which establishes whether a generic pharmaceutical has the same properties as the originator product. The joint venture was created by Indonesia's Innogene Kalbiotech and Malaysia's Info Kinetics, and will be based in a hospital in Jakarta.



PT Pharma Kinetics will be supported by PT Pharma Metric Labs, an Indonesian bioavailability/bioequivalence firm established by Innogene Kalbiotech in 2005.

Demand for services provided by PT Pharma Kinetics will increase rapidly over the next 18 months. The Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice Inspection of Manufacturers of Medicinal Products is designed to remove barriers that impede the trade of pharmaceuticals between ASEAN member states. A country's drug regulator will approve a drugmaker's plant and this certification will be accepted by fellow ASEAN states, thereby reducing a duplication of effort. Full implementation is expected by January 2011.

Overall, **BMI** forecasts that foreign sales of Indonesian-made drugs will reach US\$266.8mn by 2014, representing a CAGR of 13.59% in US dollar terms. ASEAN harmonisation will also stimulate exports, although the planned reduction of tariffs – to zero – on pharmaceuticals entering Indonesia will also increase competition posed by imports.

According to the United Nations Commodity Trade Statistics Database (UN Comtrade), Indonesia's leading pharmaceutical export partner is Thailand, closely followed by India and South Korea. The vast majority of trade is low-cost generic drugs. To move up the value chain and achieve greater margins, Indonesian drugmakers want to sell more of their products to developed countries, such as neighbouring Australia.

Exports – mainly of generics – have historically accounted for a minor share of the domestic industry's sales. Indonesia exports various types of drugs, although among the most common are low-cost, basic OTC products such as analgesics and vitamins. Exports are presently hampered by the lack of R&D investment, although joint ventures with multinationals hold significant potential for the improvement of the situation. The traditional herbal medicines market could also prove an avenue for export growth, with the trade already being worth some IDR2trn (US\$219.94mn) a year and mostly reaching South Korea, Taiwan and Hong Kong, as well as the Middle East and Russia.

## Other Healthcare Data and Forecasts

Indonesia is the fourth most populous country in the world. Its demographic profile is relatively young, although rapid population growth is increasing financial pressure on healthcare resources in the country. Over-65s account for just above 5% of the total population. Health indicators have been improving in recent years and this bodes well for the country's economic development, although the trend is a double-edged sword as healthcare resources become increasingly stretched.

## Key Risks to BMI's Forecast Scenario

Unexpectedly, rapid progress in the Indonesian government's sector reforms could have a substantial impact on **BMI**'s forecast. Should the government revive its plans to privatise its core drugs producers and align its IP rights with international standards, local industry activity could grow markedly. The catalyst for such growth is capital, with the sector in dire need of investment. Difficulties regarding economic performance, as well as an increase in political instability (including terrorism threats), could discourage high rates of activity in this field.

There is a likelihood of foreign companies investing in the country if the business environment is conducive, with such investment bringing about expansion on an even greater scale. While such a scenario was being encouraged by the proposal to remove the pharmaceutical industry from the 'negative investment' list, the position of foreign companies in Indonesia is threatened by the enforcement of the new requirements that they must have local production facilities. Legislation is affecting 13 out of the 29 foreign companies operating in the country, with the possible withdrawal of products by those 13 companies having a marked impact on the market. While some medicines shortages may be expected, the gap is likely to be filled by competitor products, marketed by both foreign and domestic drugmakers.

Nevertheless, the impact of the legislation has yet to be fully understood, with **BMI** holding its forecasts for the time being. Given their research-based nature, most companies affected by the changes are involved in the patented and branded segments, the values of which will drop in the short term if the products are withdrawn without being replaced. Additionally, there is no clear time-table for the transition, despite the fact that the requirements came into force after a two-year grace period. This leads **BMI** to suspect that the move is politically motivated and that the affected multinationals will be allowed to stay in Indonesia.

Nevertheless, the potential of the Indonesian market is considerable, given the large population and current low consumption rate. The export sector could also expand more swiftly than forecast, as producers are able to modernise and forge a stronger regional presence and take further advantage of the weak state of the currency.

## Competitive Landscape

### Pharmaceutical Sector

Indonesia has over 200 pharmaceutical manufacturers and distributors, including 29 multinationals. Despite the overhaul of Indonesia's regulatory system, its pharmaceutical sector remains a difficult position. Inadequate patent laws, uncertain government pricing policy and strong domestic capacity are largely to blame. The foreign presence is low as a result, although regional harmonisation and an improvement in business conditions will stimulate growth. Some multinationals have local plants, while others import through distributors. Indonesia has problems with transparency, corruption and red tape. The government has tried to curb corruption by mandating that all drugmakers comply with the Code of Conduct of Pharmaceutical Marketing Practice of Ethical Products. Multinationals generally adhere, but a number of local companies have failed to implement the code and there is lax monitoring and enforcement.

Additionally, in November 2008, new rules were implemented following a two-year grace period, requiring multinationals to have local production facilities. The law aims to stop the multinationals operating like retailers and to make the companies invest locally. The government order, which has drawn protests from the US Chamber of Commerce, will impact 13 international drugmakers that currently sell their medicines in Indonesia but do not have production facilities there. Among those affected include **Astellas Pharma**, **AstraZeneca**, **Eli Lilly**, **MSD**, **Novo Nordisk**, **Roche**, **Servier** and **Wyeth**.

In the coming years, however, foreign involvement may increase, following the October 2008 announcement by the Indonesian industry minister, Fahmi Idris, that he was considering removing pharmaceuticals from the national 'negative investment list'. Its current inclusion on the list means that foreign entities can only provide up to three quarters of the funds invested in a pharmaceutical concern. While **BMI** welcomes the proposal, we note that no timeframe for the transition has been given.

Unsurprisingly, the plan has the support of the IPMG and the Pharmacy Companies Association. Executive director of the IPMG, Parulian Simanjuntak was quoted as saying that, 'investing in the pharmaceutical industry requires a great amount of money. It is hard to find local partners that can inject 25% of the total funds required for the investment.'

The move would have a number of consequences. On the one hand, while local wealth will suffer through more capital leaving the country, on the other, the health of the nation will improve through increased access to cheaper medicines. We would also anticipate increased foreign direct investment by drugmakers. The negative investment list presently restricts mergers and acquisitions (M&As). Indeed, **PT Meiji Indonesia** – a subsidiary of Japan's **Meiji Seika Kaisha** – has stated that, because of the

protectionist policy, its expansion plans have been 'hampered'. Another result is that competition is decreasing and prices are rising.

## Domestic Industry

Like many other countries in South East Asia, Indonesia imports most of the raw materials needed for the production of medicines, largely because the process of making APIs is complex and costly. Most are derived from crude oil, which itself has seen significant price rises over the past year. Crude oil is refined into various substances including speciality chemicals, which are then used to create APIs. Petrochemical monomers are also manipulated to create plastics, which are vital to pharmaceutical packaging.

In late 2007, the government revealed that it planned at least 12 IPOs in 2008. The privatisation list included trading firm **Sucofindo**, metal industry company **Krakatau Steel**, construction firms **Waskita Karya** and **Adhi Karya**, and five other companies in Jakarta, Medan, Semarang, Makassar and Surabaya. By de-nationalising these assets, as much as IDR1.5trn (US\$160mn) could be raised to help cover the 2008 budget shortfall.

Prominent local firms include **Kalbe Farma**, **Combiphar** and **Sanbe Pharma**. Consolidation in the Indonesian pharmaceutical sector is part of an overall plan to privatise state-owned enterprises and is likely in the face of increased competition, pricing pressures and regional harmonisation initiatives. The government has outlined plans to merge a number of state-owned producers, such as state-controlled drug firms **Kimia Farma** and **Indofarma**. As they have limited capability to make APIs, local companies are dependent on imports, mainly from China. This undesirable situation is compounded by currency fluctuations, which in turn impact profit margins. In 2008, Indofarma and Kimia Farma recorded foreign exchange losses of US\$1.46mn and US\$428,000, respectively.

To prevent this from happening again, the new entity aims to be a full spectrum player. A chemical division will provide APIs to the pharmaceuticals business. To maintain the integrity of the supply chain, a distribution arm will link up with proprietary retail outlets. The company will also have an interest in healthcare equipment. Upon completion of the transaction, Kimia Farma and Indofarma will be removed from the Indonesian Stock Exchange and replaced by the new entity. It is possible that other state-owned firms, including **PT Biopharma**, will join the enlarged group. No employees will be dismissed during the integration phase, with news that recruitment will be accelerated to cope with diversification.

Indigenous R&D efforts are hampered by a lack of finance and widespread counterfeiting. However, in recent months, some foreign companies have started investing, with Singapore-based NITD creating a research partnership with two of Indonesia's hospitals. Despite some of its regulatory and IP shortcomings, Indonesia has potential for companies willing to conduct clinical research there, given its low costs and the epidemiological profile.

## Foreign Industry

Leading foreign players are estimated to account for around half of the market share in value terms (and a quarter in volume terms), although many are critical of numerous barriers to entry and the government bias towards generic products. Sanofi-Aventis, Pfizer, Novartis and Bayer all have manufacturing plants in the country, while a number of other multinationals – including Astellas Pharma, AstraZeneca, Eli Lilly, Merck Sharpe and Dohme (MSD), Novo Nordisk, Roche, Servier and Wyeth – only operate representative offices. The latter group will be affected by recent regulatory changes, requiring foreign companies to invest in the country.

## Recent Pharmaceutical Sector Developments

In November 2009, **Hyphens Marketing & Technical Services Pte Ltd**, a Singapore based pharmaceutical company with a strong presence in Southeast Asia, announced the signing of a distribution agreement with **PT Nicholas Laboratories Indonesia** and **PT Kebayoran Pharma** with the aim of establishing distribution channels for the company's medical products in Indonesia. Nicholas Laboratories is a locally based pharmaceutical manufacturer; while Kebayoran Pharma is a national distribution company of ethical, OTC, consumer, hospital and laboratory products with 27 branches spread over the entire Indonesian archipelago.

Under the terms of the agreement, Hyphens, which already has a registered representative office in Indonesia, will be responsible for sales and marketing activities; while Nicholas Laboratories will seek regulatory approvals for various products from the National Agency of Drug and Food Control (BPOM) Indonesia. As for Kebayoran Pharma, the company will be responsible for nationwide distribution. According to Lim See Wah, Managing Director of Hyphens, the new partnership is viewed as the first step towards gaining a growing operational presence in Indonesia. The agreement is also aimed at expanding Hyphens' collaboration with some of its existing partners and licensors in the region.

- In February 2010, **PT Roche Indonesia**, local subsidiary of Swiss pharmaceutical major **Roche**, announced that it had signed an agreement with **PT Boehringer Ingelheim Indonesia**, domestic subsidiary of German-based **Boehringer Ingelheim**, with the aim of sharing licensing and production at Boehringer's manufacturing plant in Bogor, West Java. The statement added that although the facility has an annual production capacity of up to 60mn pack units, the plant will only produce 20mn pack units this year.

For the past five years, Roche has manufactured its 30 brands of prescription-based pharmaceuticals at the manufacturing plant belonging to **PT Bayer Indonesia**. In 2004, Roche sold its pharmaceutical factory in Cimanggis, South Jakarta, divesting its consumer health business to German-based pharmaceutical giant **Bayer AG**.

- Also in November, the holding company of **PT Schering Plough Indonesia Tbk**, the **Schering-Plough Corporation**, announced that it was to officially merge with US pharmaceutical major **Merck & Co. Inc.** According to Schering Plough's Indonesia President Director, Thierry Powis, the merger was to be based on the law of the state of New Jersey. Upon completion of the merger, the legal identity of Schering-Plough Indonesia will remain despite the fact that the company will be integrated into Merck & Co. As a result of this arrangement, Schering Plough Indonesia and **PT Merck Sharp & Dohme Indonesia** will continue to run their operations separately.
- Domestic pharmaceutical manufacturer, **PT Indofarma** announced that it was targeting export sales worth IDR20-30bn (US\$2.18-3.27mn) for 2009. It is the first time that the state-owned pharmaceutical enterprise has pursued exports in its operating history. According to President Director P. Sudibyo, the aim of the export drive is to help the company overcome the impact of disparities in exchange rates. In 2008, Indofarma's net profit was reduced to IDR 17bn (US\$1.85mn) as a result of currency fluctuations. For 2009, the company forecasts exports to reach 5% of total sales. As for domestic sales, this is expected to reach IDR600bn (US\$65.53mn) for the year.
- In September 2009, US-based **Bristol-Myers Squibb (BMS)** announced that it had sold certain Asian assets to another pharmaceutical company. The candidate was Japan's **Taisho Pharmaceuticals**, which bought select OTC and consumer health products in Indonesia, Thailand and the Philippines, as well as certain other Asia Pacific countries. The medicines included *Tempra* (paracetamol), *Counterpain* (piroxicam + methyl salicylate + menthol + eugenol), *Theragran* (multivitamins), *Engran* (multivitamins), *Ceetrus* (ascorbic acid) and the *Keri* moisturiser range.
- The US\$310mn transaction also comprised BMS's 97.7% stake in **PT Bristol-Myers Squibb Indonesia**, and included land, buildings, product registrations, intellectual property, fixed assets, inventory and other items. It is expected that all 126 employees will have their contracts transferred to Taisho under the new agreement. Closure of the deal is expected during Q409.
- In July 2009, **Hard to Treat Diseases (HTDS)**, a China-based exporter of biological vaccines announced that the company was preparing a tender to export 250,000 doses of the MEVAC-ACYW Meningococcal Polysaccharide vaccine to Indonesia. It is the second completed batch to be exported to the country in 2009. The first consignment was delivered to Indonesia in December 2008 and consisted of 70,000 doses.

# Company Profiles

## Indigenous Manufacturers

### PT Kalbe Farma

#### Overview

Created in 1966, PT Kalbe Farma was the top Indonesian pharmaceutical player in 2004. Its principal activities are the production and distribution of pharmaceutical products for human and animal care. The group also manufactures foods, including nutritional supplements, and food-packaging products.

PT Kalbe Farma has more than 8,100 employees and has revenues exceeding US\$300mn. Kalbe is committed to achieving advances in the area of oncology and has an extensive reach in South East Asia and Africa.

Kalbe is looking to create its own brands which it can sell both domestically and overseas, as opposed to merely manufacturing formulations under licence, which is the common strategy among rival drugmakers. The shift in emphasis from generic to proprietary drugs is also being driven somewhat by news that the government is keen to introduce price cuts for some generic drugs in order to make them more affordable. Kalbe is reported to be meeting with investment banks and is building up a war chest of US\$60mn for acquisitions.

#### SWOT Analysis

##### Strengths

- Well-established market presence in Indonesia.
- Diverse business portfolio; active in the human and animal drug sectors, as well as the food and food-supplement industries.
- Domestic pharmaceutical regulations biased in favour of local manufacturers.

##### Weaknesses

- Relatively weak product portfolio.
- Need to source APIs through imports.
- Sector modernisation representing a threat due to likely multinational competition.
- Government regulations concerning pricing levels having a negative impact on company's profitability.
- Sizeable local manufacturing sector with a strong production capacity, hence tough competition in the domestic market.

##### Opportunities

- Well positioned for a general increase in drug consumption, due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Presence in the growing insulin market through a 10-year co-operation agreement with Singapore-based biotechnology company Sci Gen for the local distribution of insulin.

##### Threats

- Progressive government reform posing a threat to Kalbe Farma, particularly with patent law.
- Foreign company activity increasing, with the government actively seeking foreign investment.
- Any marked economic slowdown to restrain local market investment.

#### Recent Activities

In October 2006, Kalbe acquired a 49% holding in CordLife Indonesia, a cord blood banking

subsidiary of Australian drug firm Cygenics. The move will help Cordlife to expand sales by utilising Kalbe's 6,000 strong hospital sales force. Cygenics already operates similar banks in Singapore and Hong Kong, which are used to isolate and store stem cells for research as well as therapeutic purposes.

In October 2007, Kalbe Farma and CordLife opened a new cord blood processing and storage facility. The centre, the first of its kind in Indonesia, has a capacity of up to 30,000 cord blood units. CordLife already has similar facilities in Hong Kong, Singapore and Sydney.

In May 2009, according to state news agency Antara, as cited by The Jakarta Post, Kalbe is considering a buy back of 1.27bn shares – or a 12.5% stake – from the open market. The company will reserve IDR1.14trn (US\$111mn) as retained profits. It will make further decisions on selling the stake if the share prices increase.

In August 2009, Kalbe completed corporate action to increase its share ownership in PT Enseval Putera Mega Trading from 58.19% to 83.64% through a tender offer for a maximum of 725,239,000 shares. This represented 31.81% of all issued and fully-paid shares held in Enseval. During the offer period, which began on 14 July 2009 and was completed on 12 August 2009, a total of 580,161,820 shares were purchased by Kalbe. As a result, the company increased its ownership in Enseval by 25.45%, up from 58.19% to 83.64%.

In addition, Kalbe, through its wholly-owned subsidiary PT Bintang Toedjoe, acquired a 20% share ownership in domestic pharmaceutical firm PT Saka Farma Laboratories. This transaction increased kalbe's indirect shareholding in Saka Farma to 100%. Saka Farma maintains a portfolio of leading brands, including *Mextril*, *Mikorex*, *Sakatonik Liver* and *Sakatonik ABC*.

In September 2009 Kalbe announced that it was in the process of building two production plants, with one located in Bekasi and the other in Cikarang. The building program, which is estimated to cost nearly IDR200bn (US\$22.11mn), is being funded through internal sources. Although construction of the plant at Bekasi has recently been completed, work on the second facility at Cikarang is still in the process of construction, having being delayed due to the global financial crisis. According to Irawaty Setiady, Managing Director of Kalbe, the two factories could be in full operation later this year.

The expansion program at Bekasi and Cikarang is in response to the need to improve production capacity and the Indonesian government's growing demand for pharmaceuticals. At present the production capacity of Kalbe's existing factory covers only about 70% to 75% of demand. In addition to the two factories at Bekasi and Cikarang, the company has also built a production facility in Nigeria, the inauguration of which took place in May 2009. With a manufacturing factory in Nigeria, Kalbe hopes to boost its sales in the West and South African regions. Mrs. Setiady further stated that Kalbe has also signed an agreement with Cuba to conduct joint research, especially in the field of neck and head cancer.

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**Product Portfolio**

The group's pharmaceutical products consist largely of low-cost generics and include OTCs (e.g. *Extra Joss*, *Promag*, *Woods*, *Fatigon*, *OSK Puyer No.16*, *Fiber*, *Procold ND* and *Cerebrofort DHA*) and prescription drugs such as antibiotics (*Bactecyn*, *Broadced*, *Tarivid*, *Cravid*), cardiovascular drugs (including *Angioten*), CNS drugs (*Kaltrofen*) and gastrointestinal remedies (*Rantin* and



*Netrotam*).

In the first nine months to September 2005, Kalbe marketed 22 new products, which comprised seven OTC medicines, three healthfood supplements and 12 ethical drugs. The volume of new introductions increased by about 17% from 2004, of which the total rise can be attributed to 17 products. The newly marketed products comprise those offerings with new marketing brands, new formulations, products with new active elements and products with new licences. Examples of products with new marketing brands include Cerebrofit X-CEL, Starmuno, Entrasol Gold, Prenagen Emesis, and Extra Joss Baru. Those drugs with new licences comprise Mediflex, Vivotif, Hepavax-Gene and Cefizox HP. The company has also recently launched its healthcare drink Extra Joss in India.

Kalbe also has eight additional new product licences from companies in Singapore, Japan, US, Sweden, the Netherlands and Switzerland. In terms of its long-term R&D aspirations (which cover a period of three to five years), Kalbe is currently working with companies/institutions located in Germany, Spain and France to develop a number of anti-cancer and brain trauma diagnostic products.

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**Regional Operations** The company has a number of strategic alliances, including deals with Baxter, Astellas and Daiichi Pharmaceuticals. In order to enter the international market, Kalbe has established five representative offices in Sri Lanka, Malaysia, Vietnam, Myanmar and South Africa. Exports to those countries generate about 9% of the company's consolidated annual sales. The company has acquired production-licence agreements with several multinational pharmaceutical companies including France's Laboratoires Pharmaceutique Groupil, Italy's Angelini Francesco ACRAFT, and many Japanese companies, including Daiichi, Fujisawa, Kaken, Kyowa Hakko, Mitsubishi Pharmaceutical, Morinaga Milk Industry and Nippon Kayaku.

Recently, US-based YM BioSciences, a cancer product development company, created a partnership with Innogene Kalbiotech through its majority-owned subsidiary, CIMYM. The deal will expand the development programme for its humanised EGF receptor-targeting monoclonal antibody, nimotuzumab (TheraCIM). The licensed territories include Singapore, Taiwan, Thailand, Indonesia, Malaysia, the Philippines and South Africa in addition to a number of other emerging markets. Innogene will initially target head and neck cancers, for which it proposes to file an IND application in its territories for a study that will combine nimotuzumab and radiation. This will be followed by additional trials targeting other cancers. Nimotuzumab was recently approved in China, based on a study that revealed a 75% improvement in the complete response rate in patients diagnosed with squamous cell nasopharyngeal carcinoma (and 91% in patients treated with nimotuzumab plus radiotherapy, versus 52% for those treated with radiotherapy alone).

Kalbe is currently helping to develop Canadian drugmaker YM BioSciences' Theracim to treat head and throat cancer.

Kalbe is also planned to set up a joint venture factory in Nigeria. The company looked to invest between US\$2-3mn in the affiliate, with its unnamed Nigerian partner providing the remaining US\$7mn. The move came after the Nigerian government banned some drug imports as part of plans to crack down on the counterfeit drug trade. Prior to the joint-venture, Kalbe was already active in Nigeria, entering into an agreement with Orange Drugs in September 2005 to establish a joint venture pharmaceutical plant in Nigeria requiring an investment of about US\$25mn. The joint

venture entity was named Orange Kalbe, with a 70% stake controlled by Orange Drugs and 30% by Kalbe.

Kalbe announced in February 2010 that it was expanding its business in the Philippines through a joint venture agreement between Kalbe International Ltd., a subsidiary of Kalbe, and Philippines-based ARC Holdings. The aim of the agreement is to market energy drinks in the form of ready-to-drink products under the brand name *Extra Joss*. In the past, Kalbe has marketed its energy drink products in the form of sachets rather than ready-to-drink formulas. The joint venture company will comprise a respective ownership of 50% each and will be named Asiawide Kalbe Philippines, Inc., once the registration process has been completed

## Financial Performance

Figures published by Kalbe Farma for the twelve months ending 31 December 2009 reveal that the company posted net sales of IDR9.08bn (US\$999.46mn), marking a 15.4% rise over the previous year. In addition, net profits increased by 31.4% to reach IDR929bn (US\$103.17mn). Meanwhile, Kalbe's prescription pharmaceutical division recorded revenues of IDR2.21bn (US\$245.42mn), marking a rise of 17.4% compared with 2008. As a result of this robust performance, Kalbe has managed to outpace the majority of its competitors, thereby gaining a leading market share of 13.7%.

Kalbe's Consumer Health Division posted net sales of IDR1.72bn (US\$191mn), marking a 17.1% increase over the previous year. This enhanced performance was attributed to the robust demand for energy drinks, as well as improved marketing strategies. Meanwhile, sales recorded by Kalbe's Nutrition Division increased by 12.0% to reach IDR1.93bn (US\$214.32mn); while the company's Distribution and Packaging Division posted sales of IDR3.21bn (US\$356.46mn), marking a 15.1% rise over the previous year. Elsewhere, the firm's gross profit margin increased from 48.3% in 2008 to 49.6% in 2009. The rise was attributed to the strengthening of the Rupiah against several foreign currencies and a decline in the price of APIs. Kalbe also announced that both organic and inorganic growth is planned for 2010.

## Leading Products

- *Angioten*
- *Extra Joss*
- *Bactecyn*
- *Kaltofren*
- *Rantin*

## Address

- PT Kalbe Farma, Jl MH Thamrin, Blok A3-1 Lippo Cikarang, Kawasan Industri Delta Silicon, Bekasi 17550, Indonesia
- Tel: +62 21 8990 7333
- Fax: +62 21 8990 7360
- [www.kalbe.co.id](http://www.kalbe.co.id)

## Financial Highlights

- Sales (2008): US\$762mn
- Sales (2007): US\$587mn
- Net income (2007): US\$59mn
- Sales (2006): US\$509mn
- Net income (2006): US\$57mn
- Sales (2005): US\$492mn

- Net income (2005): US\$53mn
- Sales (2004): US\$423mn
- Net income (2004): US\$38mn

## PT Bio Farma

### Overview

State-owned Bio Farma is the only vaccine and serum manufacturer in Indonesia. The company is also one of the vaccine manufacturers in the world, pre-qualified by the WHO to supply the global market. Bio Farma produces serums and diagnostic tools; as well as vaccines for polio, DTP (a triple vaccine used to inoculate against diphtheria, tetanus, and pertussis), measles and a number of other infectious diseases. Annual capacity exceeds 1.1bn doses of medicine and headcount is approximately 800 employees.

In 2000, the company produced a vaccine in an auto-disable pre-fill injection device (Uniject) under joint co-operation with the Program on Appropriate Technology for Health (PATH), Becton Dickinson and UNICEF. In February 2007, Bio Farma donated 60,000 Uniject tetanus toxoid (TT) vaccines to the Indonesian Ministry of Health.

### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia.
- Strong vaccines offering, certified by the WHO.
- Domestic pharmaceutical regulations biased in favour of local manufacturers.
- The only vaccine and serum manufacturer in Indonesia.

#### Weaknesses

- Lack of diversity in its portfolio.
- Sector modernisation representing a threat, due to likely multinational competition.
- Government regulations concerning pricing levels having a negative impact on company's profitability.

#### Opportunities

- Well-positioned for a general increase in demand for medicines, due to healthcare-sector modernisation, rising health awareness and increased access to medicines.
- WHO accepting its vaccines for use by UN agencies.

#### Threats

- Progressive government reform.
- Foreign company activity increasing, with the government actively seeking foreign investment.
- Any marked economic slowdown to restrain local market investment.

### Recent Activities

Bio Farma, together with the Indonesian government, announced that it plans to start producing vaccines for the H1N1 and H5N1 strains of influenza by November 2010. The announcement was made at the inauguration ceremony of Airlangga University's Avian Influenza Research Center (AIRC), located in Bandung. The Indonesian government has allocated IDR1.3trn (US\$141.55mn) to fund the research, development and production of the vaccines. Bio Pharma will begin clinical trials in March 2010 and would start producing the H1N1 vaccine by November of the same year. The aim is to produce about 20mn doses in the first year of production.

In March 2007, the WHO in principle accepted the company's monovalent oral polio vaccine type 1, which will be purchased by UN agencies. In the previous month, Bio Farma donated 60,000 Uniject TT vaccines to the Indonesian Ministry of Health.

In October 2007, the WHO issued an acceptance in principle of the company's DTP-Heb B vaccine for the purchase by UN agencies. The vaccine has since that time been listed on the WHO website of pre-qualified vaccines. The company also produces a meningitis vaccine for prevention of pneumonia.

The government wants to combine PT Bio Farma with Kimia Pharma in an effort to realise operational efficiencies and to control costs. While BMI understands the rationale behind the strategy, very few synergies exist between the two firms and this limits potential gains. A merger is dependent on shareholder approval. The combined entity would operate under a government holding group and other drugmakers – such as Indofarma – could join the union.

The Health Legal Aid Institute (LBH Kesehatan) expressed objections in May 2008 towards a government plan to privatise Kimia Farma through an IPO, arguing that it could threaten the provision of low-priced medicines for the poor. A merger was the preferred option.

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**Financial Performance** Figures released by Bio Farma have revealed that the company made an operating profit of IDR136bn (US\$14.85mn) over the 2008 fiscal year, as compared with IDR117bn (US\$12.77mn) in 2007. However, given the prevailing financial crisis in the global economy, the company's targeted profit for 2009 is expected to reach just IDR120bn (US\$13.10mn).

In 2008, Bio Farma earned IDR805bn (US\$87.93mn) in revenue, a figure which exceeded 20% of the company's working and budgeting plans. This was more than the income earned in 2007, which stood at IDR745bn (US\$81.37mn). For 2009 however, the figure is expected to reach IDR950bn (US\$103.76mn). For the 2009 fiscal year, Isa Mansyur, President Director of Bio Farma announced that the company would be allocating IDR250bn (US\$27.23mn) as capital expenditure.

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- [www.biofarma.co.id](http://www.biofarma.co.id)

## Kimia Pharma

### Overview

Kimia Farma is the pioneer of the Indonesian pharmaceutical industry. The origin of the company can be traced back to 1917 with the establishment of NV. Chemicalien Handel Rathkamp & Co., the first pharmaceutical company in the Dutch East Indies. In 1958 the government merged a number of pharmaceutical companies into PNF Bhinneka Kimia Farma, with Kimia Farma (Persero) emerging as a modern company in 1971. Since 2001 the company has been listed at the Jakarta Stock Exchange and Surabaya Stock Exchange.

The company has two arms, namely trading and distribution and retail. The latter, PT Kimia Farma Apoket, manages over 300 pharmacies equipped with clinics and laboratories throughout the country, capturing some 19% of the total market. Kimia Farma Distribution has 40 warehouses, which supply medicines (both ethical and generic) and consumer health products.

In April 2008, the company announced that it was in discussions with potential investors to help finance the construction of a US\$100mn plant by the end of the year.

Because of intense competitive pressure, two Indonesian pharmaceutical companies agreed to merge in March 2009. Following the completion of feasibility studies and legal processes, the integration of PT Kimia Farma and PT Indofarma is expected by Q409. BMI notes that the deal once again underlines our core view that M&A activity will increase due to the efficiencies realised from consolidation.

Times are tough for Indonesian drugmakers. They have limited capability to make active pharmaceutical ingredients (APIs) and are therefore dependent on imports, mainly from China. This undesirable situation is compounded by currency fluctuations, which in turn impact profit margins. In 2008, Indofarma and Kimia Farma recorded foreign exchange losses of US\$1.46mn and US\$428,000, respectively.

### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia
- Domestic pharmaceutical regulations biased in favour of local manufacturers
- Variety of formulations on offer
- Securing the supply of APIs at affordable prices

#### Weaknesses

- Sector modernisation representing a threat due to likely multinational competition
- Government regulations concerning pricing levels having a negative impact on company's profitability
- Need to source APIs through imports

#### Opportunities

- Well positioned for a general increase in demand for medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines
- Easy access to large number of consumers and patients through expanding distribution and retail network
- Pending merger to allow new entity to capture larger market share

### Threats

- Progressive government reform
- Planned government-initiated merger to possibly result in synergy problems
- Downward pressure on prices
- Foreign company activity increasing, with the government actively seeking foreign investment
- Any marked economic slowdown to restrain local-market investment

### Recent Activities

In January 2008, Kimia Farma and Indofarm contracted a Chinese API supplier, CSPC, to provide them with bulk antibiotics. By getting a firm commitment from CSPC, the companies hope to provide a continuous and affordable supply of drugs to the Indonesian market. CSPC is one of the world's leading producers of both penicillins and cephalosporins.

However, Kimia's involvement in end-stage production may be limited by its potential merger with Bio Farma. The government wants to combine the two companies to realise operational efficiencies and to control costs. While BMI understands the rationale behind the strategy, very few synergies exist between the two firms, limiting potential gains. A merger is dependent on shareholder approval. The combined entity would operate under a government holding group and other drugmakers – such as Indofarma – is expected to be merged with Kimia. Kimia Farma is involved in manufacturing, but has to import APIs. Countering this deficiency, it has an established and wide-ranging distribution network. Further protecting margins, the company has a network of over 300 pharmacies.

The Health Legal Aid Institute (LBH Kesehatan) expressed objections in May 2008 towards a government plan to privatise Kimia Farma through an IPO, arguing that it could threaten the provision of low-priced medicines for the poor. A merger was the preferred option. The provision of low-priced medicines for the poor. A merger was the preferred option.

In April 2009, the government was looking to postpone the planned merger of state-controlled Kimia Farma and PT Indofarma – which had been scheduled for Q409. The delay is mainly due to regulatory issues. Nevertheless, the companies' shares increased by nearly 59% and 42%, respectively in March 2009, when news of the merger broke. The merger hopes to capture 15% of Indonesia's pharmaceutical market.

In January 2010, Kimia announced that it had entered into a collaborative agreement with fellow state-owned pharmaceutical manufacturer PT Indofarma with a view to building synergies and reducing risk. Through PT Kimia Farma Trading and Distribution (KFTD), a subsidiary of Kimia Farma, the company signed a Memorandum of Understanding (MoU) with Indofarma Global Medika (IGM), a subsidiary of Indofarma for the procurement and distribution of pharmaceuticals in Indonesia.

### Product Portfolio

Kimia Farma produces formulations such as coated tablet, tablet, capsule, dry syrup, electrolyte salt, oral contraceptive, syrup, ointments, cosmetic powder, suppositories and injection as well as chemicals such as iodine, iodinated salt, ferro-sulphate salts, vegetable oil, quinine, quinine crude, intrauterine devices (IUD) and herbal medicines.

The company also has a unit engaged in R&D. The facility collaborates with a number of Indonesia's institutions including Universitas Indonesia, Institut Teknologi Bandung, Universitas

Padjadjaran, Universitas Gajah Mada, Universitas Airlangga, Institut Pertanian Bogor and the Herbs and Spices Research Centre.

Kimia Farma started producing a generic version of Roche's antifu treatment *Tamiflu* (olsetamivir) in August 2006. The company was appointed by the government to manufacture the drug, which is not under patent protection in Indonesia. Kimia Farma has the capacity to produce 20mn *Tamiflu* capsules.

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**Financial Performance** Annual sales in 2007 rose 8.2% to US\$258.06mn from US\$238.49mn in 2006. Operating profit rose 10.8% to US\$8.44mn from US\$7.66mn. Net profit rose 10.8% to US\$5.68mn from US\$4.79mn. In 2008, Kimia Farma and Indofarma recorded unaudited revenues of US\$230mn and US\$120mn, respectively.

Ignoring a slight downturn in 2005, Kimia Farma has posted impressive sales growth over the last five years, occasionally reaching double figures. Assets held and equities recorded have also increased in line with revenues. However, according to company representatives only 5% y-o-y growth is expected over the mid-term as the price of raw materials booms, competition heats up and employee costs rise.

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- [www.kimiafarma.co.id](http://www.kimiafarma.co.id)



## PT Sido Muncul

### Overview

PT Sido Muncul is one of the leading domestic herbal-medicines producers, with a 15% share of the herbal medicines market. The Ministry of Health has sought to raise capital to promote the use of herbal medicines in the Central Java region, where the company is based. Its key products, including Jamu, Health Drinks, and food supplements, are also available in Russia and Eastern Europe, Malaysia, Brunei, Singapore, Switzerland, Japan, Saudi Arabia, Kuwait, the United Arab Emirates, Oman, Qatar, Bahrain and Aruba. The company is also targeting new markets including Hong Kong, Taiwan, Vietnam, New Zealand, Australia, France and the UK.

### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia.
- Domestic pharmaceutical regulations biased in favour of local manufacturers.
- One of the leading local herbal medicines producers.
- Substantial export activity.
- Some R&D investment.

#### Weaknesses

- Sector modernisation representing a threat due to likely multinational competition.
- Government regulations concerning pricing levels having a negative impact on company's profitability.

#### Opportunities

- Well positioned for a general increase in demand for medicines.
- Increasing demand for herbal medicines as some sectors of the population unable to afford modern treatments.

#### Threats

- Progressive government reform.
- Downward pressure on prices.
- Any marked economic slowdown to restrain local market investment.

**Financial Performance** In 2005 the company's profits reached IDR200mn (US\$22.99mn), up 11.1%. However, no figures for 2006 have been released publicly. Company performance has been driven by the growing preference for herbal medicines shown by Indonesian consumers.

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- [www.sidomuncul.com](http://www.sidomuncul.com)

## Combiphar PT

### Overview

Combiphar is one of the more prominent domestic producers of medicines and currently ranks 18th, up from 23rd a decade ago. The company is aiming for a top 10 ranking by 2012.

Combiphar, which was founded in 1971 as a producer of antibiotics, analgesics and a cough syrup, trades in pharmaceuticals (mostly prescription medicines) and herbal medicines.

Combiphar acquired the GMP certificate in 1991. Its production facilities in Padalarang, Bandung (West Java), were doubled to 3,000m<sup>2</sup>. The company now employs over 1,000 people. Sales are encouraged through direct promotion to medical practitioners. Its business partners include Abbott Indonesia, GSK Indonesia, Beaufour Ipsen, Fournier, Merck, Novartis, Yamanouchi Pharmaceutical Co and Vifor.

Combiphar is part of the Anugerah Corporation that also includes APT Anugerah Pharmindo Lestari (APL), a pharmaceuticals distribution company, and PT Tigaka Distrindo Perkasa (TDP), an importer and distributor of APIs and raw ingredients. Combiphar is aiming to increase efficiency through enterprise resources planning (ERP) that integrates various business processes and existing information systems (such as production, logistics, distribution and human resources).

### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia.
- Domestic pharmaceutical regulations biased in favour of local manufacturers.
- Focus on antibiotics.
- Wide range of partnerships with foreign players.
- Part of the wider conglomeration, allowing for economies of scale.

#### Weaknesses

- Sector modernisation representing a threat due to likely multinational competition.
- Government regulations concerning pricing levels having a negative impact on company's profitability.

#### Opportunities

- Well positioned for a general increase in demand for medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Application of nanotechnology to provide competitive edge.

#### Threats

- Progressive government reform.
- Foreign company activity increasing, with the government actively seeking foreign investment.
- Any marked economic slowdown to restrain local market investment.

### Product Portfolio

The main areas of Combiphar's operations are anti-infectives, alimentary tract, metabolism, cough and cold preparations, vitamins, multivitamins, minerals and cardiovascular products. The company's key products include leading H<sub>2</sub> antagonist *Zantac* (ranitidine), which was manufactured for UK major GSK prior to the establishment of a local PT Glaxo subsidiary in 1993.

In recent years the company has begun using nanotechnology in the production of pharmaceuticals, with a focus at first on the OTC area's drug delivery system. The technology used is being provided under licence from US-based Advance Pharmaceutical Nanotech.

In the course of 2006, Combiphar launched three new products that are based on nanotechnology: *Jointfit* (glucosamine, chondroitin and nano calcium plus nano vitamin D3), *Gestabil* (antacid) and *Pronemia*, a chewable double-layered tablet for patients with anemia and for pregnant women.

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- [www.combiphar.com](http://www.combiphar.com)

## Leading Foreign Manufacturers

### Sanofi-Aventis

#### Overview

As a result of the merger with Sanofi in the second half of 2004, Sanofi-Aventis has a strong position in the Indonesian pharmaceutical market. The company is Indonesia's largest foreign pharmaceutical manufacturer and also caters to the chemical and cosmetics industries. Sanofi-Aventis exports about 10% of its products to markets in Pakistan, Cambodia, Vietnam, Malaysia and Singapore, with the remaining 90% used for domestic consumption.

In a bid to boost pharmaceutical sales in certain emerging markets, multinational drugmaker Sanofi-Aventis announced that it has cut the prices of some of its drugs by as much as 50% in Indonesia. Under a tiered pricing programme, patients on lower incomes will be able to purchase drugs, including the blockbuster diabetes medicine *Lantus* (insulin glargine) and cancer medication *Taxotere* (docetaxel) at the discounted rate. The company hopes to extend the price reductions to other countries in South East Asia, including Thailand, in the near future. According to the CEO of Sanofi-Aventis, Chris Viehbacher, it is believed that emerging markets and diabetes products will be the two areas that will propel the company's sales in the future. According to BMI's *Pharmaceutical Emerging Markets Sales Index* (PEMSI), Sanofi-Aventis generates the second highest sales in non-traditional markets, after US pharmaceutical major, Pfizer. Sanofi-Aventis had emerging market sales of US\$10,222mn in 2008.

#### SWOT Analysis

##### Strengths

- Direct manufacturing presence in Indonesia.
- A strong product portfolio covering a wide range of therapeutic areas.
- A diverse domestic market presence that includes ethical pharmaceuticals, vaccines, cosmetics and chemicals.

##### Weaknesses

- Lax domestic patent law and counterfeit drugs.
- Regulatory bias towards local drugmakers.
- Significant competition on the domestic market represented by strong local producers.

##### Opportunities

- Progress in terms of ASEAN harmonisation.
- Demand for branded products is expected to rise as a result of ongoing sector modernisation.
- Potential removal of pharmaceutical industry from the 'negative investment' list.

##### Threats

- Government resistance to aligning patent law fully with internationally acceptable standards.
- Counterfeiting, poor data protection and slack law enforcement.
- Failure to revise and augment Indonesia's basic and discriminatory pricing and reimbursement policy.

#### Product Portfolio

The pharmaceuticals division focuses on cardiology, oncology, infectious diseases, arthritis, allergies, respiratory and central nervous system (CNS) disorders. Aventis sells about 50 different

ethical drugs and vaccines in Indonesia, with the most popular being the cardiovascular therapy *Lovenox*, and cancer treatments *Taxotere* (docetaxel) and *Campto* (irinotecan).

The cardiovascular market will become important in the coming years, as the epidemiological transition from infectious to non-communicable diseases gather pace. It is estimated that heart disease now accounts for 30% of deaths in Java and Bali.

Sanofi Pasteur, the vaccines unit of Sanofi-Aventis, is developing a vaccine for avian flu, which could be used in countries such as Indonesia that have high incidences of the disease. However, according to press reports, tests on Sanofi's drug have been disappointing and the company is thought to be losing out to GSK in the race to produce a viable vaccine for the H5N1 virus.

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**Leading Products**

- *Lovenox* (enoxaparin)
- *Taxotere* (docetaxel)
- *Campto* (irinotecan)

**Address**

- PT Aventis Pharma Indonesia  
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- Tel: +62 21 489 2208
- Fax: +62 21 475 1035
- [www.sanofi-aventis.co.id](http://www.sanofi-aventis.co.id)

## Pfizer

### Overview

Pfizer is one of the 29 multinationals operating in Indonesia. Given that it has direct manufacturing facilities in the country, the company is well positioned to weather the changes brought about by the recent legislation requiring foreign players to have local production or to leave the country. Pfizer also conducts some clinical research in Indonesia.

### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia.
- Direct manufacturing facilities.
- Largest global drugmaker.

#### Weaknesses

- Large segment of low-income population.
- Government regulations concerning pricing levels having a negative impact on company's profitability.
- Strong competition from other leading multinationals in the country.

#### Opportunities

- Well positioned for a general increase in demand for prescription medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Potential removal of pharmaceutical industry from the 'negative investment' list.
- Further export opportunities within the region.

#### Threats

- Progressive government reform.
- Rising demand for generics.
- Counterfeiting, poor data protection and slack law enforcement.
- Any marked economic slowdown to restrain local market investment.

### Recent Activities

Pfizer has purchased another leading US drugmaker, Wyeth, subject to regulatory approvals in various markets. In Indonesia, Wyeth markets a number of prescription products, but has no direct manufacturing presence.

### Address

- Pfizer Indonesia  
Sales Office  
Kantornya Eratel Media Distrindo  
Jakarta, Lt 11-12  
Indonesia
- [www.pfizerpeduli.com](http://www.pfizerpeduli.com)

## Novartis

### Overview

Novartis has been present in Indonesia since 1968, when it incorporated PT Ciba Indonesia. In 2005, Novartis acquired PT Prima Hexal from Hexal Group, establishing PT Sandoz Indonesia. The group employs some 550 staff in the country, some in production, some in sales and some in R&D. PT Ciba Vision Batan and PT Sandoz Indonesia are sister companies of Novartis Indonesia. The latter employs around 600 people and has a manufacturing facility in West Java. The company is presently one of the 29 multinationals operating in Indonesia and one of the few with local manufacturing facilities. Therefore, the company is well positioned to weather the changes brought about by the recent legislation requiring foreign players to have local production or to leave the country.

### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia.
- Direct manufacturing facilities, as well as local R&D operations.
- Strong generics offering.
- Wide product portfolio, including OTCs and eye care products.

#### Weaknesses

- Large segment of low-income population.
- Government regulations concerning pricing levels impacting company's profitability.
- Strong competition from other leading multinationals in the country.

#### Opportunities

- Well positioned for a general increase in demand for prescription medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Potential removal of pharmaceutical industry from the 'negative investment' list.
- Rising demand for generics.

#### Threats

- Progressive government reform.
- Counterfeiting, poor data protection and slack law enforcement.
- Lack of comprehensive reimbursement.
- Any marked economic slowdown to restrain local market investment.

### Product Portfolio

Novartis has a range of products on offer in Indonesia. These include OTCs, prescription medicines (including generics, through its Sandoz subsidiary), as well as animal health products. In the prescription segment, Novartis has a considerable strength in hypertension drugs. Novartis Eijkman Hasanuddin Research Institute (NEHCRI) – located in Makassar, Sulawesi and Jakarta – is focused on the development of treatments against tropical diseases.

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- Tel: +62 21 570 3661
- [www.id.novartis.com](http://www.id.novartis.com)

## GlaxoSmithKline (GSK)

### Overview

GSK is one of the 29 multinationals presently operating in Indonesia and one of the few with local manufacturing facilities. Therefore, the company is well positioned to weather the changes brought about by the recent legislation requiring foreign players to have local production or to leave the country.

### SWOT Analysis

#### Strengths

- One of leading global drugmakers.
- Well-established market presence in Indonesia.
- Direct manufacturing facilities.
- Wide product portfolio, including OTCs.

#### Weaknesses

- Large segment of low-income population.
- Government regulations concerning pricing levels having a negative impact on company's profitability.
- Need to source APIs through imports.
- Strong competition from other leading multinationals in the country.

#### Opportunities

- Well positioned for a general increase in demand for prescription medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Potential removal of pharmaceutical industry from the 'negative investment' list.

#### Threats

- Progressive government reform.
- Rising demand for generics.
- Counterfeiting, poor data protection and slack law enforcement.
- Lack of comprehensive reimbursement.
- Any marked economic slowdown to restrain local market investment.

### Product Portfolio

In Indonesia, GSK markets a range of human medicines, including both prescription and OTC drugs. The company provides strong support for public health programmes targeting asthma. In 2008, GSK provided IDR12.5bn in support of activities raising patient awareness of asthma.

#### Address

- GSK Indonesia  
Jalan Pulobuaran Raya  
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- Tel: +62 21 460 3292
- Fax: +62 21 460 3293
- [www.gsk.com/worldwide/id](http://www.gsk.com/worldwide/id)



## Merck & Co

### Overview

Merck & Co is present in Indonesia through its fully-owned subsidiary Merck Sharpe and Dohme (MSD). Given that it has no direct manufacturing presence in the country, the company is vulnerable to the enforcement of the requirement that foreign players either set up domestic production or leave the country.

### SWOT Analysis

#### Strengths

- One of leading global drugmakers.
- Well-established market presence in Indonesia.
- Wide prescription drug portfolio.

#### Weaknesses

- Large segment of low-income population.
- No direct manufacturing facilities.
- Government regulations concerning pricing levels having a negative impact on company's profitability.
- Counterfeiting, poor data protection and slack law enforcement negatively impacting company's position in Indonesia.
- Strong competition from other leading multinationals in the country.

#### Opportunities

- Well positioned for a general increase in demand for prescription medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Potential removal of pharmaceutical industry from the 'negative investment' list.

#### Threats

- Progressive government reform.
- Rising demand for generics.
- Lack of comprehensive reimbursement.
- Any marked economic slowdown to restrain local market investment.

### Address

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## Bayer

### Overview

Bayer has a significant presence in Indonesia, with operations at five locations across the densely populated island of Java. In addition to the Cimanggis plant, the company is present in Cibubur, Anyer/Ciwandan and Surabaya. As with all multinationals, Bayer Indonesia's headquarters are in the capital Jakarta. In addition to pharmaceuticals, the firm also makes and sells chemical products in Indonesia. Employee count is currently 875, but this is expected to rise in the mid-term.

In 2007, Bayer Indonesia was adjudged to be the 'Most Admired Company' in the pharmaceutical category. This was an improvement on their runners-up place in 2005 and 2006. The survey was conducted by *Business Week Indonesia* and involved over a thousand respondents (management, investors, journalists and the general public) ranking firms on quality, performance, responsibility and attractiveness.

Local demand for Bayer's products is solid, with 90% of local production consumed domestically. Indeed, Indonesia is the third largest market for Bayer's OTC products in Asia Pacific after China and Australia.

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### SWOT Analysis

#### Strengths

- Well-established market presence in Indonesia.
- Strong OTC portfolio.
- Local production facilities.

#### Weaknesses

- Large segment of low-income population.
- Government regulations concerning pricing levels having a negative impact on company's profitability.
- Counterfeiting, poor data protection and slack law enforcement.

#### Opportunities

- Well positioned for a general increase in demand for OTC medicines due to healthcare sector modernisation, rising health awareness and increased access to medicines.
- Recent investment in production facility to expand capacity.
- Further export opportunities.

#### Threats

- Progressive government reform.
- Lack of comprehensive reimbursement coverage to continue posing challenges to drugmakers.
- Any marked economic slowdown to restrain local market investment.

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### Recent Activities

In September 2007, Bayer made Indonesia its Asia Pacific base for consumer healthcare production. A portfolio of over a dozen OTC products will be made at its plant in Cimanggis, West Java. The medicines will then be distributed for domestic consumption and also exported to neighbouring countries.

In order to create the Asia Pacific hub, Bayer upgraded the Cimanggis facility, which it acquired from the Indonesian unit of Swiss rival Roche. The expansion project took 17 months to complete

and cost US\$24.8mn, of which just under half was spent on state-of-the-art machinery. By extrapolation, we are of the opinion that a good percentage of – if not all – output will adhere to GMP standards.

The plant expansion will allow the company to increase production capacity to 2,000 tonnes per annum, which is considerably more than the 700 tonnes previously. Ramp-up will take place gradually and full capability is expected by 2012. Well-known brands such as *Redoxon Double Action* (infection prophylactic) and *Berocca* (multivitamin) will be formulated at the facility and then sold locally as well as abroad in markets such as Malaysia, South Korea, Taiwan, China, Hong Kong and Australia.

According to The Jakarta Post, a seminar commemorating World Haemophilia Day in April 2009 ended with an appeal to the Indonesian government to provide sufficient medical facilities for the treatment of haemophilia.

Haemophilia is a hereditary genetic disorder that damages the patient's ability to control blood coagulation. The disease can cause death or can result in disability if proper treatment is not provided at early stages. Bayer is one company that is looking to raise awareness of the disease, which affects 1 in 4,000 births.

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**Financial Performance** Bayer Indonesia's export revenues are expected to increase rapidly. Sales recorded overseas from Indonesian-produced products, which reached IDR20-25bn (US\$4-5mn) in 2005, are projected to increase 7.5-fold by 2010.

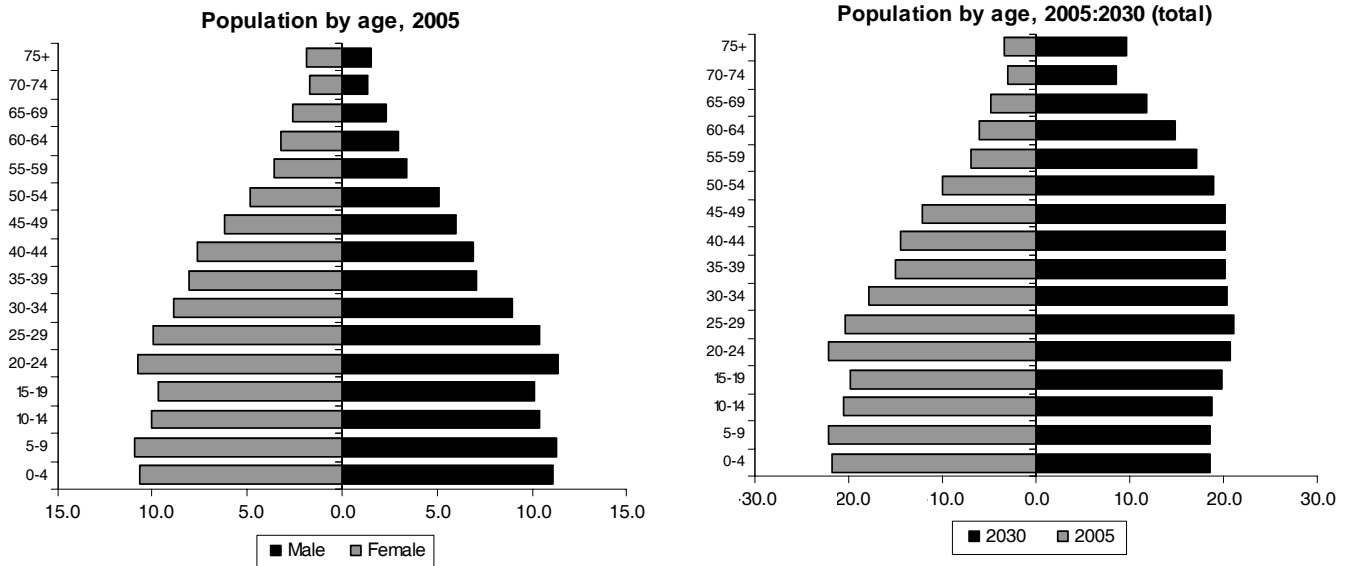
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# Country Snapshot: Indonesia Demographic Data

## Section 1: Population



Figures in millions. Source: UN Population Division

**Table: Demographic Indicators, 2005-2030**

	2005	2010f	2020f	2030f
Dependent population, % of total	34.2	33.3	30.4	30.7
Dependent population, total, '000	75,633	78,049	79,630	85,997
Active population, % of total	65.7	66.6	69.5	69.2
Active population, total, '000	144,926	156,238	182,239	193,669
Youth population*, % of total	29.1	27.7	22.8	20.0
Youth population*, total, '000	64,359	64,980	59,917	56,019
Pensionable population, % of total	5.1	5.5	7.5	10.7
Pensionable population, total, '000	11,274	13,069	19,713	29,978

f = forecast. \* Youth = under 15. Source: UN Population Division

**Table: Rural/Urban Breakdown, 2005-2030**

	2005	2010f	2020f	2030f
Urban population, % of total	47.9	53.2	62.6	68.9
Rural population, % of total	52.1	46.8	37.4	31.1
Urban population, total, '000	106,668	125,346	163,850	192,805
Rural population, total, '000	116,114	110,409	98,018	86,861
Total population, '000	222,782	235,755	261,868	279,666

*f = forecast. Source: UN Population Division*

## Section 2: Education And Healthcare

**Table: Education, 2000-2005**

	2000-2001	2004-2005
Gross enrolment, primary	115	115
Gross enrolment, secondary	59	62
Gross enrolment, tertiary	15	17
Adult literacy, male, %	94.0	na
Adult literacy, female, %	86.8	na

*Gross enrolment is the number of pupils enrolled in a given level of education regardless of age expressed as a percentage of the population in the theoretical age group for that level of education. na = not available. Source: UNESCO*

**Table: Vital Statistics, 2005-2030**

	2005e	2010f	2020f	2030f
Life expectancy at birth, males (years)	64.6	67.0	71.4	73.5
Life expectancy at birth, females (years)	68.6	70.5	75.7	77.9

*e/f = estimate/forecast. Source: UNESCO*

## Section 3: Labour Market And Spending Power

Table: Employment Indicators, 2001-2006

	2001	2002	2003	2004	2005	2006
Economically active population, '000	na	na	na	na	105,802	106,282
– % change y-o-y	na	na	na	na	na	0.4
– % of total population	na	na	na	na	46.8	46.4
Employment, '000	90,807	91,647	90,785	93,722	94,948	95,177
– % change y-o-y	1.0	0.9	-0.9	3.2	1.3	0.2
– male	57,131	58,583	59,909	60,582	60,769	61,864
– female	33,676	33,064	30,876	33,141	34,210	33,313
— female, % of total	37	36	34	35.3	36	35
Total employment, % of labour force	na	na	na	na	89.74	89.55
Unemployment, '000	8,005	9,132	9,531	10,251	10,854	11,105
– unemployment rate, %	8.1	9.1	9.5	9.9	10.3	10.5

na = not available. Source: ILO

Table: Consumer Expenditure, 2000-2010 (US\$)

	2000	2006	2007e	2008e	2009f	2010f
Consumer expenditure per capita	416	961	1,195	1,283	1,450	1,802
Poorest 20%, expenditure per capita	175	404	502	539	609	757
Richest 20%, expenditure per capita	900	2,081	2,588	2,778	3,138	3,902
Richest 10%, expenditure per capita	1,185	2,739	3,407	3,657	4,131	5,137
Middle 60%, expenditure per capita	335	774	962	1,033	1,167	1,451
<b>Purchasing power parity</b>						
Consumer expenditure per capita	1,570	2,499	2,658	na	na	na
Poorest 20%, expenditure per capita	659	1,050	1,116	na	na	na
Richest 20%, expenditure per capita	3,399	5,411	5,755	na	na	na
Richest 10%, expenditure per capita	4,475	7,123	7,576	na	na	na
Middle 60%, expenditure per capita	1,264	2,012	2,140	na	na	na

e/f = BMI estimate/forecast. na = not available. Source: World Bank, Country data; BMI calculation

**Table: Average Annual Manufacturing Wages, 2000-2012 (IDR)**

	<b>2000</b>	<b>2006</b>	<b>2007e</b>	<b>2008e</b>	<b>2009f</b>	<b>2010f</b>	<b>2012f</b>
Wages, IDR	5,096	11,740	12,717	13,777	14,811	15,881	18,267
Wage growth, % y-o-y	30.15	15.37	8.32	8.33	7.51	7.22	7.28

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*e/f = BMI estimate/forecast. Source: ILO, BMI*

## BMI Methodology

### How We Generate Our Pharmaceutical Industry Forecasts

Pharmaceutical sub-sector forecasts are generated using a top-down approach from **BMI**'s Drug Expenditure Forecast Model. The semi-automated tool incorporates historic trends, macroeconomic variables, epidemiological forecasts and analyst input, which are weighted by relevance to each market. The following elements are fed into the model:

- **BMI**'s historic pharmaceutical market data, which have been collected from a range of sources including:
  - regulatory agencies;
  - pharmaceutical trade associations;
  - company press releases and annual reports;
  - subscription information providers;
  - local news sources; and,
  - information from market research firms that is in the public domain.
- Data that have been validated by **BMI**'s pharmaceutical and healthcare analysts using a composite approach, which scores data sources by reliability in order to ensure accuracy and consistency of historic data.
- Five key macroeconomic and demographic variables, which have been demonstrated, through regression analysis, to have the greatest influence on the pharmaceutical market. These have been forecast by **BMI**'s Country Risk analysts using an in-house econometric model.
- The burden of disease in a country. This is forecast in disability-adjusted life years (DALYs) using **BMI**'s *Burden of Disease Database*, which is based on the World Health Organization's burden of disease projections and incorporates World Bank and IMF data.
- Subjective input and validation by **BMI**'s pharmaceutical and healthcare analysts to take into account key events that have affected the pharmaceutical market in the recent past or that are expected to have an impact on the country's pharmaceutical market over the next five years. These may include policy/reimbursement decisions, new product launches or increased competition from generics.



## Pharmaceutical Business Environment Ratings Methodology

Our approach in assessing the Pharmaceutical Business Environment Ratings is threefold. First, we have defined the risks rated to capture the operational dangers to companies operating in this industry. Second, we attempt where possible to identify objective indicators that may serve as proxies for issues/trends. Finally, we use **BMI**'s proprietary Country Risk Ratings (CRR) to ensure only the aspects most relevant to the industry are included. Overall, the system, which is integrated with all the industries covered by **BMI**, offers an industry-leading insight into the prospects/risks for companies across the globe.

## Ratings Overview

### Ratings System

Conceptually, the new ratings system divides into two distinct areas:

*Limits of potential returns:* Evaluation of sector's size and growth potential in each state, and also broader industry/state characteristics that may inhibit its development.

*Risks to realisation of those returns:* Evaluation of industry-specific dangers and those emanating from the state's political/economic profile that call into question the likelihood of anticipated returns being realised over the assessed time period.

### Indicators

The following indicators have been used. Overall, the rating uses three subjectively measured indicators, and 41 separate indicators/datasets.

Table: Pharmaceutical Business Environment Indicators

Indicator	Rationale
<b>Limits to potential returns</b>	
<b>Market structure</b>	
Market expenditure, US\$bn	Denotes breadth of pharmaceutical market. Large markets score higher than smaller ones
Market expenditure per capita, US\$	Denotes depth of pharmaceutical market. High value markets score better than low value ones
Sector value growth, % y-o-y	Denotes sector dynamism. Scores based on annual average growth over five-year forecast period
<b>Country structure</b>	
Urban-rural split	Urbanisation is used as a proxy for development of medical facilities. Predominantly rural therefore states score lower
Pensionable population, % of total	Proportion of the population over 65 years of age. States with aging populations tend to have higher per-capita expenditure
Population growth, 2003-2015	Fast-growing states suggest better long-term trend growth for all industries
Overall score for <i>country structure</i> is also affected by the coverage of the power transmission network across the state	
<b>Risks to potential returns</b>	
<b>Market risks</b>	
Intellectual property (IP) laws	Markets with fair and enforced IP regulations score higher than those with endemic counterfeiting
Policy/reimbursements	Markets with full and equitable access to modern medicines score higher than those with minimal state support for healthcare
Approvals process	High scores awarded to markets with a swift appraisal system. Those that are weighted in favour of local industry or are corrupt score lower
<b>Country risk</b>	
Economic structure	Rating from CRR evaluates the structural balance of the economy, noting issues such as reliance on single sectors for exports/growth, and past economic volatility
Policy continuity	Rating from CRR evaluates the risk of a sharp change in the broad direction of government policy
Bureaucracy	Rating from CRR denotes ease of conducting business in the state
Legal framework	Rating from CRR denotes the strength of legal institutions in each state. Security of investment can be a key risk in some emerging markets
Corruption	Rating from CRR denotes the risk of additional illegal costs/possibility of opacity in tendering/business operations affecting companies' ability to compete

Source: BMI

## Weighting

Given the number of indicators/datasets used, it would be wholly inappropriate to give all sub-components equal weight. Consequently, the following weight has been adopted.

**Table: Weighting Of Components**

Component	Weighting
<i>Limits of potential returns</i>	60%
– Pharmaceutical market	75%
– Country structure	25%
<i>Risks to realisation of potential returns</i>	40%
– Market risks	60%
– Country risk	40%

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Source: BMI

## Sources

Sources used include national industry associations, government ministries, global health organisations, officially released pharmaceutical company results and international and national news agencies.

Table: Indonesia – Pharmaceutical Expenditure Indicators, Historical Data and Forecasts

	2005	2006	2007	2008	2009	2010f	2011f	2012f	2013f	2014f	2015f	2016f	2017f	2018f	2019f
Drug market expenditure (US\$bn)	2.43	2.53	2.65	2.76	2.92	3.66	4.24	4.82	5.38	5.97	6.79	7.71	8.46	9.26	10.13
Drug market expenditure (IDRbn)	23,629.3	23,052.8	24,284.6	26,888.6	30,257.2	33,457.1	37,089.8	41,177.3	45,735.9	50,721.7	56,029.0	61,670.4	67,668.6	74,104.6	81,025.8
Per capita drug market expenditure (US\$)	10.75	11.04	11.44	11.75	12.31	15.24	17.46	19.63	21.69	23.80	26.80	30.12	32.72	35.49	38.42
Drug market expenditure as % GDP	0.85	0.69	0.61	0.58	0.60	0.60	0.59	0.58	0.57	0.56	0.55	0.55	0.54	0.53	0.52

*f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI*

Table: Indonesia – Healthcare Expenditure Indicators, Historical Data and Forecasts

	2005	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f
Health expenditure (US\$bn)	6.34	8.98	10.73	12.26	13.14	16.98	20.60	24.58	28.82	33.43
Health expenditure (IDRbn)	61,593.77	81,929.53	98,305.46	119,649.86	136,071.42	155,364.79	213,371.11	224,913.42	252,152.68	285,822.60
Health expenditure (% GDP)	2.22	2.45	2.48	2.59	2.68	2.76	2.85	2.95	3.04	3.14
Health expenditure per capita (US\$)	28.03	39.25	46.32	52.29	55.37	70.75	84.86	100.17	116.15	133.34
Public sector health expenditure (US\$bn)	2.96	4.53	5.58	6.62	7.36	9.85	12.39	15.32	18.61	22.38
Public sector health expenditure (%)	46.64	50.42	52.00	54.00	56.00	58.02	60.12	62.31	64.58	66.94

*f = forecast. Source: World Health Organization (WHO), BMI*

Table: Indonesia – Prescription Drug Market Indicators, Historical Data and Forecasts (US\$mn unless otherwise stated)

	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f	2015f	2016f	2017f	2018f	2019f
Prescription drug market (US\$bn)	1.51	1.58	1.67	1.78	2.19	2.54	2.89	3.23	3.58	4.08	4.64	5.10	5.59	6.12
Prescription drug market (IDRbn)	13,760.6	14,512.6	16,260.6	18,406.9	20,023.4	26,293.6	26,418.3	28,251.0	30,643.5	34,705.8	39,434.1	42,041.2	44,693.2	48,922.4
Prescription drug market as % total market	59.69	59.76	60.47	60.83	59.85	59.90	59.95	60.00	60.06	60.12	60.18	60.25	60.31	60.38

f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI

Table: Indonesia – Prescription Drug Market Indicators, Historical Data and Forecasts (IDRmn)

	2005	2006	2007	2008	2009	2010f	2011f	2012f	2013f	2014f
Alimentary tract and metabolism drug sales	1,695,443.35	1,590,611.92	1,677,540.46	1,879,589.81	2,127,695.67	2,314,541.91	3,039,333.51	3,053,740.26	3,265,586.86	3,542,146.93
Blood and blood forming organ drug sales	1,386,208.87	1,300,497.80	1,371,571.31	1,536,768.58	1,739,622.03	1,892,389.10	2,484,984.87	2,496,763.95	2,669,971.53	2,896,089.38
Cardiovascular system drug sales	2,873,946.03	2,696,246.28	2,843,598.84	3,186,092.70	3,606,656.94	3,923,380.01	5,151,974.25	5,176,395.14	5,535,496.31	6,004,293.28
Dermatological drug sales	357,329.15	335,235.03	353,555.96	396,139.59	448,430.01	487,809.45	640,565.46	643,601.81	688,250.29	746,537.68
Genito-urinary system and sex hormone sales	574,730.54	539,194.21	568,661.72	637,153.50	721,257.76	784,595.91	1,030,289.68	1,035,173.35	1,106,986.26	1,200,736.08
Systemic hormonal preparation, excluding sex hormones and insulins, sales	386,092.08	362,219.51	382,015.17	428,026.53	484,526.03	527,075.29	692,127.27	695,408.03	743,650.45	806,629.64
Anti-infective for systemic use sales	1,584,249.18	1,486,293.03	1,567,520.44	1,756,318.56	1,988,152.61	2,162,744.71	2,840,001.48	2,853,463.38	3,051,416.21	3,309,838.32
Antineoplastic and immunomodulating agent sales	1,407,051.36	1,320,051.58	1,392,193.72	1,559,874.82	1,765,778.30	1,920,842.32	2,522,348.12	2,534,304.31	2,710,116.16	2,939,633.84
Musculoskeletal system drug sales	722,300.05	677,639.32	714,672.99	800,750.92	906,450.04	986,051.08	1,294,829.91	1,300,967.53	1,391,219.33	1,509,040.64
Nervous system drug sales	2,050,132.35	1,923,370.05	2,028,484.15	2,272,802.50	2,572,812.43	2,798,747.15	3,675,166.12	3,692,586.78	3,948,751.97	4,283,168.77
Antiparasitic product, insecticide and repellent sales	17,894.33	16,787.90	17,705.37	19,837.87	22,456.47	24,428.52	32,078.23	32,230.29	34,466.19	37,385.11
Respiratory system drug sales	1,156,794.81	1,085,268.71	1,144,579.74	1,282,437.27	1,451,718.99	1,579,203.50	2,073,726.17	2,083,555.84	2,228,098.00	2,416,793.93
Sensory organ drug sales	239,695.96	224,875.25	237,164.91	265,729.95	300,806.31	327,221.99	429,690.53	431,727.31	461,677.46	500,776.57
Various drug sales	215,626.62	202,294.15	213,349.73	239,046.39	270,600.51	294,363.63	386,542.68	388,374.94	415,317.60	450,490.54

f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI

Table: Indonesia – Patented Drug Market Indicators, Historical Data and Forecasts

	2005	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f	2015f	2016f	2017f	2018f	2019f
Patented products (US\$bn)	1.08	1.05	1.06	1.08	1.11	1.34	1.53	1.71	1.86	2.01	2.24	2.47	2.63	2.80	2.95
Patented products (IDRbn)	10,536.7	9,565.9	9,745.0	10,533.3	11,538.6	12,261.3	15,802.2	15,621.9	16,245.3	17,208.6	18,998.3	20,999.1	21,728.1	22,361.0	23,626.5
Patented market as % total market	44.59	41.50	40.13	39.17	38.13	36.65	36.00	35.45	34.50	33.73	32.91	32.05	31.14	30.17	29.16

f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI

Table: Indonesia – Generic Drug Market Indicators, Historical Data and Forecasts

	2005	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f	2015f	2016f	2017f	2018f	2019f
Generics market (US\$bn)	0.4	0.5	0.5	0.6	0.7	0.8	1.0	1.2	1.4	1.6	1.8	2.2	2.5	2.8	3.2
Generics market (IDRbn)	4,130.7	4,194.7	4,767.6	5,727.2	5,727.2	5,727.2	10,491.5	10,796.4	12,005.7	13,435.0	15,707.5	18,435.0	20,313.1	22,332.3	25,295.9
Generics market as % total market	17.5	18.2	19.6	21.3	22.7	23.2	23.9	24.5	25.5	26.3	27.2	28.1	29.1	30.1	31.2

f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI

Table: Indonesia – OTC Drug Market Indicators, Historical Data and Forecasts (US\$m unless otherwise stated)

	2005	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f	2015f	2016f	2017f	2018f	2019f
OTC market (US\$bn)	0.92	1.02	1.07	1.09	1.14	1.47	1.70	1.93	2.15	2.38	2.71	3.07	3.36	3.68	4.01
OTC market (IDRbn)	8,961.8	9,292.3	9,772.0	10,628.0	11,850.2	13,433.7	17,603.7	17,648.7	18,830.1	20,376.5	23,021.1	26,090.7	27,742.1	29,411.4	32,103.4
OTC market as % total market	37.93	40.31	40.24	39.53	39.17	40.15	40.10	40.05	40.00	39.94	39.88	39.82	39.75	39.69	39.62

f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI

Table: Indonesia – OTC Drug Market Indicators, Historical Data and Forecasts (IDRmn)

	2005	2006	2007	2008	2009	2010f	2011f	2012f	2013f	2014f
Analgesic drugs sales	1,075,420.80	1,133,655.84	1,074,920.00	1,296,616.00	1,303,524.20	1,638,917.43	2,147,654.88	1,941,352.06	2,071,313.68	2,241,418.50
Cough & cold drugs sales	1,666,902.24	1,700,483.76	1,824,017.90	1,944,924.00	2,211,933.42	2,458,376.14	3,221,482.32	3,294,255.30	3,514,785.50	3,803,434.18
Digestives	52,785.24	56,682.79	42,996.80	54,202.80	52,140.97	68,512.12	107,382.74	77,654.08	82,852.55	89,656.74
Skin treatments	1,318,286.66	1,370,939.30	1,441,717.88	1,568,008.35	1,748,329.31	1,981,956.27	2,597,176.64	2,603,804.91	2,778,113.69	3,006,263.84
Vitamins and minerals sales	2,159,803.44	1,879,824.40	1,983,716.00	2,150,044.40	2,405,594.66	2,717,647.51	3,561,234.28	3,582,676.98	3,822,515.25	4,136,435.96
Other OTC sales	2,688,552.00	3,151,005.71	3,404,564.80	3,614,582.80	4,128,616.65	4,568,818.18	5,969,424.34	6,148,791.43	6,560,415.33	7,099,183.69

f = forecast. Source: Association of the European Self-Medication Industry (AESGP), IMS Health Asia, GP Farmasi, AC Nielsen, BMI

Table: Indonesia – Medical Device Market Indicators, Historical Data and Forecasts

	2005	2006	2007	2008	2009	2010f	2011f	2012f	2013f	2014f
Medical device market (US\$bn)	0.17	0.19	0.21	0.24	0.27	0.31	0.35	0.40	0.45	0.49
Medical device market (IDRbn)	1,603.80	1,705.25	1,939.26	2,338.02	2,811.74	2,816.61	3,616.52	3,624.09	3,930.83	4,147.03
Medical device market as % of total healthcare market	2.60	2.08	1.97	1.95	2.07	1.81	1.69	1.61	1.56	1.46

f = forecast. Source: US Commercial Service, BMI

Table: Indonesia – Pharmaceutical Trade Indicators, Historical Data and Forecasts (US\$mn)

	2005	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f
Exports	64.90	82.50	96.50	128.20	141.07	162.12	185.23	210.41	237.63	266.79
Imports	126.90	165.90	204.10	215.90	254.88	298.21	345.76	397.24	452.20	510.00
Balance	-62.00	-83.40	-107.60	-87.70	-113.81	-136.09	-160.53	-186.83	-214.58	-243.21

f = forecast. Source: United Nations Commodity Trade Statistics Database, International Trade Centre (ITC), BMI

Table: Indonesia – Other Health Indicators, Historical Data and Forecasts

	2005	2006	2007	2008	2009f	2010f	2011f	2012f	2013f	2014f
Hospitals	1,227	1,252	1,263	1,286	1,307	1,324	1,343	1,362	1,380	1,399
Beds per 000 population	0.64	0.63	0.62	0.61	0.60	0.59	0.58	0.57	0.56	0.55
Doctors per 000 population	0.21	0.22	0.23	0.23	0.24	0.25	0.25	0.26	0.27	0.28
Births per 000 population	21.50	21.30	21.50	21.40	21.20	21.25	21.21	21.17	21.13	21.09
Deaths per 000 population	7.29	7.28	7.27	7.26	7.25	7.24	7.23	7.22	7.21	7.20

f = forecast. Source: Indonesia Ministry of Health, BMI

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