

May 11-17, 2013

TPP trade pact a lopsided deal?

Secretive trade agreement suggests if Malaysia does not stand its ground, it may lose more than it gains

➔ **IN FREE** trade agreements, it is common for countries to forgo some trade liberties in exchange for greater access to other markets. However, in the case of the Trans-Pacific Partnership (TPP) negotiations, now in their third year and 16th round of talks, this trade-off remains unclear for Malaysia.

In fact, some observers say that Malaysia may end up getting the short end of the stick, while the US and other developed nations will get the lion's share from the TPP agreement.

"The US sees the economic potential in Malaysia and Asean, and it probably wants to take advantage of developments in this region. It is not clear if Malaysia could harvest greater benefits from its trade with the US through the TPP than it is able to enjoy right now," says Malaysian Institute of Economic Research senior research fellow Dr Shankaran Nambiar.

While the working text of the agreement remains inaccessible to the public, the initial 29 chapters of the draft have been leaked and their contents have sparked protests by NGOs and civil groups around the world. Some of the controversial chapters include the intellectual property and investment chapters, which critics say will give added advantage to foreign companies that hold patents and copyrights, and to foreign investors from other countries that are signatories to the TPP.

"Malaysian negotiators may be going for an extensive market-access deal for Malaysian products into the American market; but even then, it is really difficult to assess whether the economic gains will be completely offset by the increased expenditure on patented medicines," says Malaysian AIDS Council (MAC) policy manager Fifa Rahman, who attended the stakeholders sessions at TPP negotiations.

Serious implications

Increased expenditure on patented medicines is one of the possible risks that Malaysia may face should it agree to certain provisions in the intellectual property chapter of the TPP agreement.

"Numerous patient groups and public health organisations are united across the globe in denouncing arbitrary provisions that serve Big Pharma's interests, including data exclusivity, patent extensions and data linkage," says Fifa.

These provisions could delay Malaysia's access to cheaper generic drugs by up to 10 years. "Each medicine is subjected to a [minimum] 20-year patent period by the World Trade Organisation. In the TPPA, however, they are asking for an extension of five years," Fifa says.

She adds that the US is asking for an additional number of years of data exclusivity, when all data and information about the medicine is made exclusive to the company that invented the drug.

This means generic drug manufacturers, which rely on this data to develop generic versions of innovator (or original) drugs, would not be able to start developing cheaper drugs until the patent expires. In addition, the process



Leaders of the Trans-Pacific Partnership Agreement member states met at the sidelines of the Apec Summit in Japan in 2010. From left are former Japanese prime minister Naoto Kan, former Vietnam president Nguyen Minh Triet, Australian Prime Minister Julia Gillard, Chile President Sebastián Piñera, Singapore Prime Minister Lee Hsien Loong, US President Barack Obama, New Zealand Prime Minister John Key, Sultan of Brunei Hassanal Bolkiah, former Peru president Alan García, and Malaysian Deputy Prime Minister Tan Sri Muhyiddin Yassin



by LIM WEY WEN

of development itself can be expected to take some years.

While this does not affect governments' ability to subsidise medicines, it may mean that the country has to pay premium prices for drugs for a longer period. And if these drugs are not covered under state subsidies, patients would also have to pay these higher prices for longer.

Another worrying provision is the investor-state dispute settlement, which critics say allows corporations to take governments to court if the companies can prove that regulations made by these governments may hurt their future profits. "Basically, an environmental regulation that expropriates the profits of the polluting corporation could subject the regulating government to international arbitration at tribunals like the International Centre for Settlement of Investment Disputes (ICSID)," Fifa says.

The effects of such a provision have been experienced by countries including Australia, Peru and Uruguay. In 2011,

New York-based investment company Renco Group filed a US\$800 mil (RM2.4 bil) international suit against the Peruvian government under investor-state dispute settlement provisions in the US-Peru Free Trade Agreement, after the government tried to take measures to mitigate the health and environmental repercussions brought about by one of the company's smelters in the country.

According to reports, the suit was filed after the Peruvian government cancelled the company's operating licence for the La Oroya smelter in July 2010, after it failed to complete an environmental clean-up project. In 2005, scientists had found that 97% of children under six years old in La Oroya had toxic levels of lead in their blood.

Tobacco manufacturer Philip Morris International is also currently involved in trade litigation against Uruguay and Australia, for trying to pass laws that would mandate the plain packaging of tobacco products.

A provision in the TPP's government

procurement chapter, which calls for fair, transparent and non-discriminatory procurement, has also rattled the Malay Chamber of Commerce Malaysia and the Malaysia Muslim Consumers' Association. Both organisations have raised concerns that Malay businesses may not be able to compete with multinational corporations (MNCs) and that trade preferences given to them may be abolished.

Former prime minister Tun Dr Mahathir Mohamad has also commented that "what the US wants most is access to contracts for government procurements. This is something which every country, including the US, uses to support domestic businesses and industries. Once the US gains access, not only will it make bids but their government pressure would also be used to favour their companies".

Other Malaysian civil groups that have protested these controversial provisions are the Consumers' Association of Penang (CAP), Malaysian AIDS

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The Trans-Pacific Partnership agreement

- The Trans-Pacific Partnership (TPP) was built upon the Trans-Pacific Strategic Economic Partnership (TPSEP) that was signed by New Zealand, Singapore, Chile and Brunei in 2005. Australia, Canada, Mexico, Peru, Malaysia and Vietnam joined the talks shortly after the US announced its entry into the talks in 2009.
- Sixteen rounds of negotiations have been held in all 11 countries, and the next round is going to be held in Lima, Peru from May 15 to May 24. The 18th

- round of negotiations is expected to be held in Malaysia at the end of July.
- The US Trade Representative (USTR) office summarised the TPP as a 21st-century agreement that will enhance trade and investment, promote innovation, economic growth and development, and support the creation and retention of jobs.
- It is more than a free-trade agreement, as it covers non-trade issues such as sanitary and phytosanitary measures, rules

- of origin, Customs cooperation, investment, services, non-conforming measures, financial services, telecommunications, e-commerce, business mobility, government procurement, competition, intellectual property, labour, the environment, capacity-building, trade remedies and legal and institutional matters, on top of market access and technical barriers to trade.
- Negotiators aim to conclude the talks by October this year.

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Intellectual property rights area of concern

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Council (MAC), Positive Malaysian Treatment Access & Advocacy Group (MTAAG+), Jaringan Rakyat Tertindas (Jerit) and the Coalition against FTA – a coalition that includes the Federation of Malaysian Consumers Associations (Fomca).

“Our position on the TPP is that the interest of the people should come first,” says Fomca deputy president Muhammad Sha’ani Abdullah. “However, the whole negotiation is so secretive that even members of parliament are not privy to the details. This, in itself, is in violation of the people’s right to information.”

Charles Santiago, DAP’s Klang Member of Parliament, has also been very vocal against the agreement. “Study upon study has shown that free trade agreements do not bring in investments. Instead, it is structures and human capital that attract investors,” he has said.

Search for a win-win agreement

The US is clear about what it wants from the TPP. “The TPP will be an ambitious, next-generation, Asia-Pacific trade agreement that reflects US economic priorities and values. Through this agreement, the Obama Administration is seeking to boost US economic growth and support the creation and retention of high-quality American jobs, by increasing exports to a region that includes some of the world’s most robust economies and that represents more than 40% of global trade,” says the US Trade Representative (USTR) website.

“The Obama Administration, working in close partnership with Congress and with a wide range of stakeholders, is working to conclude a strong agreement that addresses the issues that US businesses and workers are facing in the 21st century,” it continues.

On the surface, the US is offering preferential access to all goods and services that are traded in the US and lowered tariffs for some of these goods in exchange for similar market access to 10 other TPP-negotiating countries. However, the downside is that the 10 other countries are expected to conform to US standards of doing business.

According to the USTR, the agreement will include “cross-cutting issues



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“Malaysia recognises the importance of a strong IP regime, to foster innovation and investment in high-technology areas.”

— MITI

not previously seen in trade agreements, such as making the regulatory systems of TPP countries more compatible so US companies can operate more seamlessly in TPP markets, and helping innovative, job-creating, small- and medium-sized enterprises participate more actively in international trade”.

However, the Ministry of International Trade and Industry (Miti), which is negotiating the agreement for Malaysia, rubbishes claims that Malaysia will end up being disadvantaged, arguing that Malaysia as a trade-dependent nation will gain from joining the TPP.

“The TPP will eventually offer Malaysia duty-free access to the markets of the US, Canada, Mexico and Peru,” says the ministry in an emailed reply to **FocusM**.

“(It) is viewed by many as a vehicle towards the creation of the FTA of the Asia-Pacific which, once realised, would encompass a market of almost 2.7 billion people,” Miti adds.

While the Malaysian government has stated that it has done a cost-benefit analysis into entering the TPP pact, the results of the analysis were not released to the public. “As with all FTAs, the TPP offers both opportunities and challenges,” Miti says.

“Market access negotiations are complex, considering we are dealing with 11 countries, each with their own areas of interest and sensitivity. Malaysia is seeking flexibility in implementing market-access commitments for sensitive sectors.

“On competition, Malaysia has implemented the Competition Act and does not see much difficulty with the commitments. However, with regard to proposals on disciplines on state-owned enterprises, the challenge is to ensure that these disciplines introduced do not erode the ability of governments to provide public goods and services, while allowing for healthy competition in the domestic market.”

Miti also acknowledges that intellectual property rights (IPR) are also an area of concern. “Malaysia recognises the importance of a strong IP regime, to foster innovation and investment in high-technology areas,” the ministry says.

“Malaysia currently subscribes to the World Trade Organisation (WTO)



The US embassy in Kuala Lumpur. The US sees the economic potential in Malaysia and Asean, and it doubtless wants to take advantage of developments in this region

agreement on Trade-Related Aspects of Intellectual Property Rights (Trips) and the challenge in the TPP is to strike a balance between protecting the rights of the IP holders and providing access to affordable medicines and healthcare,” it adds.

According to leaked portions of the TPP intellectual property chapter, these flexibilities are to be limited. The Trips agreement is a minimum-standards agreement administered by the WTO, which requires members to protect intellectual property rights in their countries but provides for flexibilities in areas that concern public health and promote competition.

On investor-state dispute settlement (ISDS) provisions, Miti says that the provisions are a way to ensure that foreign investors feel confident that their investments are protected. “There are many Malaysian companies operating abroad and ISDS offers them similar assurances,” the ministry says.

Impact of implementation

A world trade expert says a free-trade agreement is not a “sign-and-forget affair”, adding that the implementation of the agreement would continue to be refined by task forces set up by the countries involved.

Although the scenarios painted by critics of the TPP are a cause for concern, there is no way to determine whether they will unfold if Malaysia signs the TPP agreement until the provisions in the agreement are implemented.

“Even after the negotiating countries sign the agreement, they could release

the text of the agreement only four years after that,” says MTAAG+ president Edward Low, who has been following the negotiations since they began three years ago.

He notes that while Miti has held several public consultations with stakeholders, there was no clear answer to queries about the ways the TPP could benefit Malaysia. “This is what we want our government to answer,” he says.

When asked about the criticisms of the TPP, Miti says that the Malaysian government acknowledges and shares the concerns of stakeholders and is addressing them in negotiations.

“The TPP’s agenda is to liberalise and facilitate trade and investment – with the aim of ensuring that members continue to enjoy economic growth and development.

“However, Malaysia will not agree to commitments which would negatively impact the country and its citizens. The goal is to arrive at a mutually-beneficial agreement, which addresses both Malaysia’s interests and concerns in a balanced manner,” Miti says.

As Malaysia seeks more room to market its products, it may see the TPP as a ticket to markets such as the US, after the Malaysia-US FTA talks were suspended indefinitely in 2009.

However, with the secrecy surrounding negotiations, it is up to our negotiators to ensure that the benefits of opening our market to an economic superpower equal or outweigh the potential risks Malaysian consumers and businesses may be exposed to once the deal is inked. **FocusM**

Miti to minimise impact of TPP changes

WHILE the Trans-Pacific Partnership negotiations are ongoing, it may be premature to say if there will be a need to make major changes to legislation and policies, says the Ministry of International Trade and Industry (Miti).

“Malaysia is working to ensure that the goals of the agreement are met with minimal impact on current legislations and policies,” it says in an emailed reply to **FocusM**.

According to Miti, Malaysia strongly supports the TPP initiative, as it is expected to “have a positive overall impact on the economy”.

“The negotiations are progressing well across all areas, including those of interest to Malaysia, such as market access in goods, services, investment, SMEs and cooperation- and capacity-building.

“The areas of concern are state-owned enterprises and intellectual property rights. The government will consider these issues carefully before making any commitments,” it says, adding that the negotiating team is constantly in consultation with stakeholders and will seek flexibility in negotiations, to take on board

Malaysia’s concerns.

Miti confirms that all negotiating parties have agreed to keep the negotiations confidential, adding this is necessary as negotiations are between governments and each of the members has its own laws on confidentiality.

However, Miti says the confidentiality undertaking has not hampered its ability to conduct comprehensive domestic consultations with relevant stakeholders.

Despite speculation that the talks may be delayed beyond the intended deadline

in October this year, Miti says that Malaysia hopes to see continued the spirit of cooperation between negotiating parties, so that the October target can be realised.

Increased expenditure on patented medicines is one of the risks that Malaysia may face should it agree to certain provisions in the intellectual property chapter in the TPP agreement



Hidden costs of private healthcare

Much of the rise in Malaysian healthcare costs has less to do with inflation and more to do with profit

→ **FIVE** years ago, the normal delivery of a child in a Klang Valley private medical facility would cost an average of RM2,000.

Today, a check with several private healthcare facilities in the area has revealed it will cost between RM3,000 and RM5,000 – a figure which may not include laboratory tests, meals and other charges.

This marks a 10% average annual increase, a rate more than quadruple the official inflation rate, which has averaged 2.5% for the past five years.

The ballooning of medical costs in public and private sectors has not gone unnoticed; the Health Ministry has since 2009 been looking into addressing these costs through the 1Care for 1Malaysia healthcare transformation plan.

The difference is the public-sector cost is largely absorbed by government subsidies, while those who head for private hospitals are starting to feel the pinch. Stories about families seeking donations from the public for their loved one's medical care after having exhausted all their savings, including having sold their houses, are sadly common.

While skyrocketing healthcare costs may be attributed to the need for investment in better care and increased therapeutic options in the private sector, there is a pervasive feeling that there is an unnecessary padding of bills, says Malaysian Medical Association (MMA) president Datuk Dr NKS Tharmaseelan.

"Those who pay with some form of medical cover are known to pay higher bills and sometimes patients are admitted unnecessarily, as third parties do not pay if patients are not admitted," he explains.

Sickness means big business

While doctors' consultation fees are capped by the Health Ministry's fee schedule, there are no regulations or guidelines for private hospital charges that include accommodation, amenities, nursing and the professional fees



Members of the public waiting for their turn to be served at a public hospital



by LIM WEY WEN

of allied health professionals (which include dietitians and physiotherapists).

Tharmaseelan's views are echoed by many private healthcare medical professionals, from private hospital doctors to laboratory personnel, as well as by pharmaceutical salespeople and insurance agents.

One laboratory technician points out that a battery of tests to check a person's liver condition is about two times more expensive in a private hospital than at a commercial laboratory, while several pharmaceutical sales personnel revealed that mark-ups on medication and other chemical products can range from 20% to 100%.

"It depends on the drugs and the hospital," says a former pharmaceutical salesperson, who adds that not all hospitals impose such high mark-ups.

Medical Practitioners Coalition

Association of Malaysia (MPCAM) president Dr Jim Loi puts it bluntly. "Medicine is now a business," he says.

Indeed it is big business now, with major hospital chains in Malaysia such as KPJ Healthcare Bhd and Parkway Pantai (under IHH Healthcare Bhd) recording double-digit growth last year. KPJ Healthcare posted close to a 10% increase in revenue for FY12, after four years of double-digit growth since 2008. Parkway Pantai recorded a 49.8% jump in revenue in FY12.

However, there is a difference between making a profit and profiteering, says Medical Defence Malaysia Bhd board member Dr Milton Lum.

"When the commercialisation of healthcare crept in, there tends to be an emphasis on the financial bottom line and not on the patient," he says.

"Five years ago, a RM100,000 medical bill was very uncommon. Today, it is not that uncommon anymore," adds Lum, who is also a consultant obstetrician and gynaecologist.

with particular services.

While problems with phantom charges and repeated tests are less heard of here, excessive mark-ups, billing errors, delays that lead to longer hospital stays, unnecessary tests or procedures and discriminatory billing are the more prominent complaints, according to healthcare-industry observers.

For example, it was reported several years ago that a breast cancer patient was billed for a bilateral mammogram when she in fact had just one breast done – she'd had a mastectomy of the left breast more than 10 years before.

In obstetrics and gynaecology, unnecessary procedures may take the form of a Caesarean section when it is not indicated, says Lum.

In other areas of specialisation, unnecessary procedures may include unwarranted laparoscopic surgeries, going ahead with operations although the patient is at high risk of compli-

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Capping escalating healthcare costs

A STANDALONE law to regulate managed-care organisations (MCOs) and third-party administrators (TPAs) in the private-healthcare sector may be introduced to control healthcare costs and avoid overcharging.

According to Malaysian Medical Association president Datuk Dr NKS Tharmaseelan, the Ministry of Health (MOH) has seriously considered drafting a standalone MCO Bill or incorporating amendments to the Private Healthcare Facilities Services Act 1998, as proposed by the association.

According to the Act, an MCO is any organisation or body that has an agreement or contract with a healthcare service provider (eg a hospital or a clinic) to

provide healthcare services to policyholders upon agreed-on payment arrangements with the healthcare service provider. TPAs process group insurance policies for an employer.

In 1994, the Malaysian government allowed MCOs to operate in the country.

In 2008, more than 50 MCOs in the country were required to register with the Health Ministry to effectively regulate their dealings with other private healthcare facilities or service providers.

At the time, only six registered.

Some of the more prominent MCOs include PMCare Sdn Bhd and the MHC Asia Group, while TPOs include Medijaring Sdn Bhd, Asia Assistance Network (M) Sdn Bhd and MediExpress (Malaysia) Sdn Bhd.

Errors, delays and 'primitive' requirements

According to the US' Illinois Legal Aid website, some of the top 20 ways US hospitals overcharge patients include excessive mark-ups, delays that lead to longer hospital stays, paying for wasteful hospital practices and discriminatory billing to self-payers. In the US, patients without medical insurance are said to pay more for the same services because hospitals may shift some of the hospital costs away from third-party payers (like Blue Cross and Medicare/Medicaid).

Other ways include billing for services not rendered, duplicate billings, repeated tests due to poor testing and phantom charges for items associated



Tharmaseelan says splitting of fees is not permitted by the Medical Act, but it continues to be done



Loi says it may not be possible to do without insurance companies or managed-care organisations, as escalating healthcare costs have made it difficult for patients to pay medical bills out of their own pockets



New diagnostic tests and better equipment have been touted as one of the factors that have raised medical costs over the years

Patients must be told of estimated bills

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cations, and recommending excessive check-ups, he adds.

An insurance agent reveals that those with medical insurance sometimes get taken on a “check-up tour” they may not need. She relates the story of a friend, referred to an eye specialist and even a gynaecologist when she saw a neurologist for numbness in half her face.

However, like many patients who have medical coverage, checking her medical bill was the last thing on this friend’s mind.

“In the end, it is still the patient’s choice,” says Lum, adding that doctors have a duty to provide their patients with all the information they need for an informed decision.

The Private Healthcare Facilities Services Act 1998, which provides rules for and controls over private healthcare services, stipulates that a private hospital has a legal obligation to inform patients of anticipated bills, Lum points out. However, not many hospitals comply, he adds.

According to the MMA, private hospitals claim to provide patients to be admitted with a checklist in which they explain their room rates and other charges.

“However, this may not include the full list of miscellaneous charges that may crop up during the course of a hospital stay,” says the MMA’s Tharmaseelan.

Private hospitals generally maintain that cash-paying patients and those paying under managed-care organisations will not be differentiated billing-wise, as the charges code keyed into the system by billing staff is the same.

Nevertheless, patients under managed-care organisations may be charged a refundable additional deposit if they want to go home before the organisations verify the final hospital bill on discharge, which may be delayed.

The hidden middlemen

Aside from hospitals, there are third parties – such as managed-care organisations, insurance agencies, and pharmaceutical and medical-device

suppliers – that need to profit.

Managed-care organisations (MCOs), sometimes also called third-party administrators (TPAs), are companies employed by large employers or insurance companies to manage financing and healthcare delivery by healthcare providers (such as hospitals and clinics) to employees or insurance policyholders.

Patients or employers must pay the third party a fee and sometimes private hospitals and doctors are “forced” to give a discount for the volume of patients received from these parties.

“Such splitting of fees is not permitted by the Medical Act, but it continues to be done,” says Tharmaseelan.

According to Mohd Adzahar Abdul Wahid, executive director of PMCare Sdn Bhd (a managed-care organisation), MCOs or TPAs do not own insurance licences and do not provide coverage for patients.

“MCOs or TPAs manage and administer the delivery of healthcare for the members, who are either employees or their dependants in an organisation or policyholders of an insurance company.

“The claims that patients managed and administered by MCOs or TPAs are often hit with increased medical bills are not true and, as of today, there is no documentary evidence to support

those claims,” says Mohd Adzahar.

He explains that the challenges of rising medical bills is experienced by everyone that requires healthcare services, due to rising drug costs, related goods and services, new schools of thought about treatment threshold levels in certain illnesses as well as patient insistence on certain treatments that they come to know of through the Internet.

“Doctors are [also] exposed to legal suits nowadays. To avoid legal suits, doctors carry out certain tests to dispel the concern of a patient, although the tests are later proven negative,” he says.

It may not be possible to do without insurance companies or managed-care organisations, as escalating healthcare costs have made it difficult for patients to pay medical bills out of their own pockets, explains MPCAM’s Loi.

Large organisations may also need these parties to manage their employees’ medical benefits, as they hire more staff or as their staff require more medical treatment as they age.

However, Tharmaseelan and Loi call for the regulation of private hospital charges as well as managed-care organisations and third-party administrators. “The [Health] ministry has assured MMA that a fee guideline may be introduced to regulate fees charged by hospitals,” Tharmaseelan says.

“It is quite difficult to regulate hospital charges, as each hospital is different and the operating costs of these hospitals are not the same.”

— ADZAHAR



Hisham says issues with private hospital charges are ongoing challenges and the ministry is addressing them to find a balance acceptable to all

“When, we do not know, but it is essential and the government must look seriously into the matter,” he adds.

However, Mohd Adzahar argues it is quite difficult to regulate hospital charges, as each hospital is different and the operating costs of these hospitals are not the same.

“What probably could be done is that for a basic service and for a specific treatment, some form of standardisation of charges can be formulated by all the stakeholders – the hospitals, the Health Ministry and the payers – which may be represented by the MCOs or TPAs,” he says, adding that the stakeholders first need to agree on the definition of “basic services”.

Currently, patients unhappy with their medical bills can seek explanation from the hospital and, if the elaboration is deemed unsatisfactory, they may file a complaint with the Health Ministry.

In 2012, the Health Ministry reportedly launched an investigation into complaints that patients with medical insurance were being overcharged by private hospitals.

No results have been announced

When contacted, Health Ministry director-general Datuk Dr Noor Hisham Abdullah tells **FocusM** that issues with private hospital charges are ongoing challenges and the ministry is addressing them to find a balance acceptable to all.

While he says it is too early to announce the steps taken by the ministry, he concedes that the first step is to listen to both sides and understand the situation. **FocusM**



Lum says doctors have a duty to provide their patients with all the information they need for an informed decision

Peddling fake drugs online

Purveyors of pharmaceuticals widen distribution channels to Internet

➔ **COUNTERFEIT** medicines, estimated to account for 3-6% of the RM4.5 bil Malaysian medicine market, used to be peddled at the *pasar malam* or roadside stalls. However, unscrupulous purveyors of fake pharmaceuticals have now widened their distribution channel to the Internet, taking advantage of Malaysians' penchant for online shopping.

Since Malaysia started working with Interpol on Operation Pangea in 2012, the Ministry of Health's Pharmaceutical Services Division (PSD) has identified more than 200 websites (including Malaysian-based ones) selling illegal medicines. Operation Pangea is an annual, Interpol-coordinated, one-week operation to combat the sale of illegal medicines online.

In the same period, over 2,000 parcels of medicines suspected to contain illegal substances were confiscated by the ministry.

The trend of selling fake medicine online can be deduced from the fact that counterfeit medicines seized by the division's pharmacy enforcement officers have declined in recent years.

In 2010, counterfeit medicines made up 362 of the 11,934 medicinal products seized by the division's enforcement officers. In 2011, 344 counterfeit medicines were seized out of 17,768 medicinal products. However, the numbers took a dive last year as only 116 counterfeit products, valued at RM33,149, were seized out of 27,836 medicinal products valued at RM22.1 mil.

This development came to light when the Health Ministry reported an increase in websites selling illegal pharmaceuticals – unregistered products, banned products and counterfeit products.

These websites may be attractive due to discounts, the ease of purchasing certain controlled medicines without prescription, or the availability of illegal substances. For instance, anabolic steroids, a controlled drug in Malaysia, are attainable through certain blogs or websites.

According to the PSD, counterfeit medicines mostly involve popular over-the-counter medicines and prescription drugs of particular interest, such as erectile dysfunction drugs, slimming medications and general health preparations.

"We do not track individual complaints, but as a general consensus,



In Malaysia, counterfeit medicines mostly involve popular over-the-counter medicines and prescription drugs of particular interest such as erectile dysfunction drugs, slimming medications and general health preparations



there is a reduction in counterfeit cases," says Pharmaceutical Association of Malaysia (PhAMA) executive director Ewe Kheng Huat.

"However, this is an ongoing issue and [with enforcement and regulatory authorities] we will need to be vigilant all the time."

He notes that based on external reports, the association noticed a trend of counterfeits shifting from lifestyle concoctions (such as pills for erectile dysfunction and slimming) to life-saving products and products for chronic illnesses (such as antibiotics, anti-asthmatics and medicines for diabetes and high blood pressure); from street peddlers to the existing supply chain and the Internet sale of pharmaceuticals.

"My major concern is that of cheap alternatives being sold at community pharmacies without prescription and control by the Health Ministry, which lends itself to possible abuses and possibly parallel imports of either genuine, fake or 'replica' drugs," says Dr David KL Quek, a cardiologist and former Malaysian Medical Association president.

He says cheaper drugs may mean the drugs are bought illegally, and possibly from a dubious chain-of-sale which includes fakes and possibly poorer storage and handling, which mean the drug content may be compromised and not what is indicated on the label, or even be out of date and re-labelled by unscrupulous agents.

This applies to innovator drugs (sometimes called original or branded drugs) as well as generic drugs, which should not be confused with counterfeit drugs.

Generics are drugs produced by manufacturers after an innovator drug's patent has expired. Although they are cheaper than innovator drugs, manufacturers of generics have to prove the drugs are pharmaceutically equivalent before their products can be registered with the National Phar-

Ministry's fight against counterfeits

THE Health Ministry's (MoH) efforts to combat counterfeit medicines started in the 1970s with the setting up of the Pharmacy Enforcement Unit on Jan 1, 1976.

Currently, there are about 450 pharmacy enforcement officers who conduct routine and scheduled inspections on manufacturers and retailers at entry points, raids, and the prosecution of those who are involved in counterfeiting activities.

However, as the penalties stipulated by current laws, such as the Sales of Drugs Act 1952, are too low, they do not provide the deterrent effect, Health Ministry Pharmaceutical Services Division (PSD) senior director Datuk Eisah A Rahman tells *FocusM*.

There is also no specific definition of counterfeit medicines in the Acts enforced by the Pharmacy Enforcement Division.

"Counterfeit, or fake medicine [stealing the identity of popular products], are only defined under the Trade Description Act enforced by the Ministry of Domestic Trade, Cooperatives and Consumerism," says Eisah.

However, the division still routinely investigates and confiscates counterfeit medicines when found in the market. The division was recently acknowledged for its work against trafficking in fake medicines when it received the National Public Body Award at the Global Anti-Counterfeiting Group 2013 Global Anti-Counterfeiting Awards.

To overcome the challenges in combating counterfeits, a Pharmacy Bill would be tabled in Parliament by year-end.

Under the current Sales of Drugs Act, individuals charged with selling counterfeit medicines face a RM50,000 fine or a



Eisah...consumers are advised to purchase medicines from reliable sources such as licensed pharmacies or clinics

jail term not exceeding three years, while companies risk a RM100,000 fine.

Under the Pharmacy Bill, the penalties proposed for individuals convicted of the offence are a jail term of four to 15 years and a fine of up to RM2 mil. Companies face up to a RM5 mil fine and their owners could also face a jail term of four to 15 years.

Deterrents aside, counterfeit medicines cannot be eradicated without the participation of consumers, who are the counterfeiters' main target group. "Consumers are advised to purchase medicines from reliable sources such as licensed pharmacies or clinics," says Eisah.

"Please avoid buying from street peddlers, night markets or from illegal websites which offer medicines at lower prices, with huge discounts or those with exaggerated medical claims as the source of such medicines cannot be ascertained and they might be counterfeit medicines," she adds.



by LIM WEY WEN



It may be difficult to tell counterfeit medicines from genuine innovator or generic drugs

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Some counterfeits sold at higher prices

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maceutical Control Bureau to be sold in Malaysia.

The World Health Organisation defines counterfeit medicines as medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source. This may include products without active ingredients, with insufficient active ingredients or with fake packaging.

Not necessarily cheaper

While it is generally believed that the easiest way to spot counterfeit drugs is their lower prices, industry sources say counterfeit drugs are not necessarily cheaper than market prices.

They reveal that some counterfeiters or retailers sell their products at similar if not higher prices, compared to innovator or generic drugs, to allay suspicion.

Furthermore, these counterfeiters and retailers make much more selling their goods at higher prices. "It is not easy to spot [counterfeits] as most counterfeit medicines are made exactly [like] the real ones," says a community pharmacist, who spoke on condition of anonymity.

The only way to avoid purchasing counterfeit drugs is to avoid purchasing drugs from unknown sources, she says.

She also notes that as pharmacists in private establishments often play the dual role of pharmacist and businessman, price wars happen and cashflow pressures may induce some pharmacists to opt for cheaper options.

"Sometimes runners will go to pharmacies and offer pharmacists cheaper drugs and sell to them without receipts. There is no way to determine the source of these drugs," she says.

Even the hologram tags used to prevent counterfeit drugs can be faked. In November last year, the Health Ministry introduced the newest version of the Meditag III hologram in its ongoing effort to combat counterfeit drugs.

"The Meditag III displays [a] new image to make it difficult for those who have the intention of making fake holograms. It also has characteristics that add value to the existing Meditag, to help enforcement agencies, industry players and consumers verify the authenticity of products available in the market," says Health Ministry Pharmaceutical Services Division senior director Datuk Eisah A Rahman in a circular announcing the change.

The Meditag III is the second upgrade since the hologram was introduced in 2005. The last upgrade to enhance security features and the ease of recognition was in 2006.

According to the Health Ministry's PSD director of pharmacy enforcement Mohd Hatta Ahmad, counterfeit medicines are found mostly in unregulated markets such as night markets and roadside stalls.

He notes that while there have been one or two incidents where some counterfeit medicines have been found in pharmacies and clinics, they were isolated cases.

When contacted by **FocusM**, Malaysian Pharmaceutical Society president Datuk Nancy Ho says she is confident



Consumers should purchase medicines from reliable sources such as licensed pharmacies or clinics

the society's members are vigilant and careful about the source of their medication. "They realise that counterfeit medicines may cost lives and some may not be effective," she says.

Although she acknowledges there may be a few unscrupulous individuals in the industry, she insists these are "isolated black sheep".

Counterfeit danger

An estimate published by the US Center for Medicine in the Public Interest in 2009 pegs the worldwide sales of counterfeit medicines that year at US\$75 bil (RM245 bil) – a sharp 90% rise in five years.

But even the World Health Organisation admits it is difficult to measure the extent of the problem when there are so many sources of information and different definitions of "counterfeit". Nevertheless, the dangers of counterfeit medicines extend beyond profits – they endanger lives.

One incident was reported in 2008, when 150 people in Singapore were admitted to hospital in the first five months with severely low blood-sugar levels. They were reported to have taken counterfeit copies of drugs that were said to treat erectile dysfunction but contained a hefty dose of glybu-

ride, a drug used for treating diabetes. According to the World Health Organisation, four died and seven suffered severe brain damage.

"Our concern is more on the impact [of counterfeit medicines] on patients' safety and their wellbeing," says PhAMA's Ewe.

"A counterfeit product may have no active ingredients, contain too much of a particular ingredient or [contain] harmful substances," he says, adding that members of the pharmaceutical association are collaborating with authorities to assist in training and creating awareness among patients.

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Fake drugs still prevalent in Asia

- In 2009, 20 million bottles and sachets of counterfeit and illegal medicines were seized in a five-month operation coordinated by the International Criminal Police Organisation (Interpol) across China and seven of its Southeast Asian neighbours; 33 people were arrested and 100 retail outlets closed.
- The Federation of Indian Chambers of Commerce and Industry claims that 15-20% of medicines on sale in India are fake, although the Indian government says the rate is 0.04% based on its own research.
- A 2006 study in Laos, Myanmar, Vietnam and Cambodia found that 68% of artesunate (anti-malaria) drugs did not contain the correct amount of active ingredient.
- From Sept 25 to Oct 3, 2012, Malaysia's Health Ministry Enforcement Division identified 96 websites selling unregulated pharmaceuticals under the Pangea V operation. From June 18 to 26 this year, under the Pangea VI operation, the division identified 131 websites conducting similar sales.
- Due to the conservative nature of Malaysian society, erectile dysfunction (ED) therapeutics are the most frequently copied medicines on the market, estimated to account for 30-40% of all counterfeit medicines.

How consumers can protect themselves

WHILE health authorities and enforcement agencies have the responsibility of ensuring medicines available in the market are genuine and safe, consumers can also protect themselves from the dangers of counterfeit medicines.

Malaysian Pharmaceutical Society president Datuk Nancy Ho recommends that consumers build a good relationship with their pharmacist and establish their credibility.

Pharmacists are obliged to display their licence in their pharmacies, but it is important for consumers to build trust and good communication with these professionals. "Consumers should carefully assess the establishment and ensure that

they are dealing with a professional who has taken an oath to uphold a code of ethics," she says.

"They must not be too price-conscious to the point where they forgo the professional services rendered," she adds.

Consumers could also look for the Meditag hologram on the packaging of medicines, and check their authenticity using a Meditag decoder that is supplied by the Health Ministry to all licensed pharmacies and pharmacy enforcement branches nationwide.

Federation of Malaysian Consumers Associations (Fomca) deputy president Sha'ani Abdullah says it is normal for consumers to be price-sensitive and

the responsibility of ensuring that only genuine medicines are sold lies with the authorities.

"Cheap does not mean illegal... and [the authorities] cannot expect all consumers to be aware, educated and conversant," he says.

He acknowledges that consumer education is important, but enforcement should come first. "As it is a regulated sector, it is the authorities' responsibility to ensure that consumers would be able to obtain legal products at affordable prices.

"After that, consumer education should be given to fill the enforcement gap," he says.