FOCUS

The Medical Devices Industry Stands Up and Shines

BIZ UPDATE

Arab Health 2014: Exhibition and Congress

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CEO's NOTES



IN this issue of *TradeMart*, we put the spotlight on the medical devices sector.

There is no doubt that changing demographics, a more affluent society and more health-conscious lifestyles have led to the creation of a healthy domestic industry.

While the industry has been dominated by the public healthcare sector, there has been tremendous growth of private healthcare services as well.

However, much effort is still needed to develop the industry further. Towards this end, the government aims to further grow this sector by encouraging more private investments in areas such as manufacturing of pharmaceutical products and medical devices, clinical research, aged-care services and supporting collaborative efforts between public and private healthcare providers.

Collectively, 40 healthcare projects announced under the Healthcare NKEA are expected to create 26,966 jobs and generate an income of RM6.59 billion, as well as RM4.96 billion in new investments by 2020.

The Association of Malaysian Medical Industries (AMMI) estimated this year's export outlook to be RM16.88 billion, a 10% growth from last year (RM15.35 billion). The domestic market is expected to grow by 15.9% per year and to hit US\$2.8 billion by 2017.

Elsewhere, we make a virtual tour of Oatar, the world's third-largest natural gas field provider, in our Exporters' Guide section. Deemed to be the world's richest country per capita, Qatar is currently positioning itself as a world-class tourism hub under the Qatar National Tourism Sector Strategy 2030.

Last but not least, our regular contributor AB Teoh, author of Exporting and International Trade, offers some tips in his column on effective ways for local companies to enter a foreign market.

Happy reading!

DATUK DR WONG'LAI SUM

Chief Executive Officer

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Malaysia is currently the world's leading producer and exporter of catheters and surgical & examination gloves, supplying 80% of the world market for catheters and 60% for rubber gloves.

Other exports of medical devices which registered strong growth included cannulae, needles, medical and surgical instruments and appliances as well as orthopaedic appliances.

While the industry is still dominated by the production of rubberbased products comprising mainly medical gloves, catheters and condoms, there is a gradual shift towards the manufacture of non-rubberbased higher value medical devices made from plastics, silicone and metal alloys.

Mainly, the industry is characterised by small to medium-sized enterprises, with some multinational companies. The industry is capital and technology-intensive and employs over 20,400 people, most of whom are at the managerial, profes-

sional, supervisory and technical staff levels.

As the global environment for the medical devices industry becomes more competitive with new and innovative products being rapidly developed, manufacturers are expanding and widening their base into higher value products and increasingly moving into product and process R&D as well as design and prototyping.

Higher technology processes are utilised such as new materials, better coating for improved performance, increased automation and more efficient processing technologies.

The R&D activities undertaken include improvements to process control and product quality, product development such as latex compound formulations and process design of safety needles.

By 2015, the value of Malaysia's

medical device market is expected to reach RM5.08 billion (US\$1.64 billion).

Malaysia is also the gateway to Asia – a region with the fastest-growing economies and where 75% of the world's population resides.

Asia's healthcare market constitutes approximately 34% of the global healthcare market. A diverse range of medical equipment and products are imported to cater for Asia's growing healthcare needs.

Medical devices companies in Malaysia also have the advantage of the close proximity to the Asean market. With the full realisation of the Asean Free Trade Area (AFTA), medical devices manufacturers will benefit from a single market with a total population of more than 580 million people, a combined GDP of US\$1.2 trillion and total trade of US\$1.62 trillion.









MALAYSIA'S THRIVING HEALTHCARE AND MEDICAL DEVICES INDUSTRY

OMPLIANCE with global regulations such as that of the European Commission and the United States' Food and Drug Administration (FDA) remains a challenge for the Malaysian healthcare and medical devices industry players to penetrate high value market such as the US and Europe.

Given the industry's highly regulated nature, MATRADE is adopting the blue ocean strategy by focusing on the least fierce market, according to Mohamad Sabri Ab Rahman, MATRADE's Director of Health and Environmental Products Section.

"One of the strategies is to engage in less stringent market in order for Malaysian companies to build their market share and reputation before they begin engaging in more fierce market such as US and Europe," he tells TradeMart. 'Some of the companies – particularly rubber glove manufacturers – have already penetrated the US and European markets successfully."

In 2013, the US is Malaysia's largest medical devices market with 24.9% market share (RM2.97 billion), followed by Germany 12.78% (RM1.53 billion), Japan 6.68% (RM797.46 million), Singapore 5.95% (RM710.9 million) and Belgium 5.18% (RM618.94 million).

Surgical and examination rubber

gloves remained as the major exports under the medical devices products category, accounting for 68.9% of the total medical devices products export in 2013.

Meanwhile, exports of other medical devices (excluding medical gloves) also surged by 28% to RM4.34 billion from RM3.39 billion in 2012. Ophthalmic lenses, including contact lenses, registered the most significant expansion, climbing 90.20% to RM533.33 million from RM280.41 million.

Singapore was the biggest market with export value of RM414.26 million (92.5% from RM215.22 million) followed by Germany (more than 300% increase to RM35.93 million from RM7.5 million).

On new prospects, MATRADE is eyeing new European, Central Asian and ASEAN member countries. "Turkey, Uzbekistan and Kazakhstan are some of the countries which we could visually perceive huge potential," Mohamad Sabri points out.

The Turkish medical devices market is targeted to grow by 3.4% over the 2013-2018 period. In 2013, the Turkish medical device market was estimated at US\$2.42 billion, of which 85% of its market is supplied by imports.

Among the Central Asian countries, Uzbekistan is the leading im-



Mohamad Sabri Ab Rahman

porter of Malaysian products. The strategic location of Uzbekistan has provided it an edge as an important importer and distributor to other countries within the region.

Over the last 10 years, Uzbekistan has spent more than US\$750 million to continuously upgrade and modernise its healthcare sector.

"For the existing ASEAN market such as Myanmar, MATRADE will assist the SMEs to penetrate this market through more focus programmes such as the GoEx programme. This programme offers customised advisory and marketing assistance by appointed Market Advisors and Market Linkers to SMEs to significantly improve their export performance. As for the rest of the existing markets, MATRADE is continuously promoting the industry through direct meeting with potential buyers," adds Mohamad Sabri. 1



GROWING THE MEDICAL DEVICES INDUSTRY

HE Association of Malaysian Medical Industries (AMMI), formed in 1989, represents leading medical devices manufacturing companies in Malaysia.

AMMI chairman Hitendra Joshi says members share a common commitment to quality and are reputable international and local firms that adhere strictly to the quality management system codes laid down by governmental agencies.

The AMMI member companies continue to be the growth base of the medical devices industry in Malaysia and consist of three main types of industry players: manufacturers, suppliers of raw materials, and importers and exporters of medical devices.

As at September 2014, AMMI represented 50 companies that collectively account for more than 40% of the total export revenue for Made in Malaysia medical devices.

"Throughout the year,

we have successfully influenced the enactment of the Medical Devices Act in Malaysia and also pioneered graduate training programmes to support the growth of the medical devices industry," says Joshi.

AMMI also supported government initiative to make the medical devices sector as National Key Economic Area (NKEA) under the Economic Transformation Programme.

Since its inception 25 years ago, AMMI has succeeded in spearheading the development of the

medical devices industry and its eco-system.

"The industry has grown from being a predominantly producer of quality and more advanced technology," he says.

According to Epsicom's "The World Medical Markets Fact Book 2013", the medical devices industry market in Malaysia was estimated to

be worth RM4.663 billion (US\$1.437 billion) in 2013.

"Malaysia is the world's leading producer and exporter of medical gloves, catheters and condoms, supplying 60% to 65% of rubber gloves, 80% of the world's market for catheters, and has been the largest exporter of

condoms in terms of quantity since 2010," he says.

Today, Malaysia is recognised as the medical devices manufacturing hub of the Asean region.

"With the Asean Economic Community (AEC) coming soon, Malaysia is expected to take a leading role in the medical devices manufacturing technology space," he adds.

Moving forward, AMMI's Strategy for 2015 is to focus on manufacturing and operational excellence which will promote and strengthen best in class manufacturing operations in Malaysia, and identify and promote appropriate processes, structures and policies to facilitate manufacturing and operational excellence.

"We estimate that this year's export outlook for the medical devices industry will hit RM16.88 billion, 10% up from the industry's total exports of RM15.35 billion last year," says Joshi.



Hitendra Joshi

ASSOCIATION OF MALAYSIAN MEDICAL INDU

ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES PERSATUAN INDUSTRI PERUBATAN MALAYSIA



rubber-based products to a producer of higher value medical devices made from plastics, silicone and metal alloys," he says.

Devices of high value manufactured in Malaysia are orthopaedic products, intravenous catheters, dialysers, surgical instruments, medical electrodes, diagnostic radiographic equipment, pacemakers, defibrillators and ophthalmic lenses.

"It is a challenging industry that AMMI faces to access the domestic market due to the perception by local decision-makers that imported devices are of better



APHM RAISES STANDARD OF HEALTHCARE



HE Association of Private Hospitals of Malaysia (APHM) was set up to coordinate the activities of private hospitals in Malaysia, with the aim of facilitating the delivery of healthcare of the highest standards to the public.

APHM was registered in 1972 and currently has 123 members from all over Malaysia, out of the 220 private hospitals licensed by the Ministry of Health.

It is also focused on promoting cooperation amongst member hospitals and other healthcare providers.

One of the core objectives of APHM is to develop and maintain a uniformly high standard of patient care, skills, services and professionalism in private hospitals.

With the support from the Ministry of Health and other agencies, APHM continues to play a significant role in the promotion of patient safety and quality of healthcare delivery.

The association also exchanges experiences and information with other hospitals in both Malaysia and overseas on cost effect management and training for staffs. It regularly organises seminars, courses and workshops in its effort to enhance knowledge and professional development.

The Annual International Healthcare Conference & Exhibition has been ongoing since 1993. Its prominent activities include training programmes for healthcare providers, which include the yearly conference and exhibition and regular smaller group workshops

on clinical and administrative/managerial topics.

APHM also provides working dialogues with public sector agencies including the Ministry of Health, permanent membership in committees of the Ministry of Health such as the National Patient Safety Coun-



cil, Managed Care, 1 Care, Medical Devices and Medical Advertisement Board, and active participation in the Asian Hospital Federation.

In the past, APHM had been coorganising with MATRADE trips to ASEAN countries to provide health talks and promote Malaysia as a health tourism destination.

The Malaysia Healthcare Travel Council (MHTC) was established by the government to formulate strategic plans for the promotion of healthcare travel services and to spearhead promotional activities for the Malaysian healthcare travel industry.

Serving as a focal point for all

matters relating to healthcare travel, MHTC works closely with the APHM and relevant government agencies and private bodies in ensuring quality care and facilitating smooth entry for healthcare travellers.

APHM is the co-founder, together with the Ministry of Health and Malaysian Medical Association (MMA), of the Malaysian Society for Quality in Health (MSQH), which is an internationally recognised accreditation body.

APHM has also obtained recognition from the Ministry of Health as the association representing private hospitals.

ARAB HEALTH 2014:

ATRADE participated in Arab Health 2014, the Middle East's leading healthcare exhibition and congress held in Dubai, UAE from 28-30 January 2014.

Established 39 years ago, Arab Health provides a platform for the world's manufacturers, wholesalers and distributors to meet the medical and scientific community in the Middle East and subcontinent.

The exhibition and congress was organised by Informa Life Sciences Exhibitions and held at the Dubai International Convention & Exhibition Centre.

With more than 3,900 exhibiting companies from 63 countries and 19 healthcare conferences with an estimated 9,000 delegates, Arab Health is a much anticipated event in the global medical events calendar.

A total of 15 Malaysian companies occupying 16 booths participated under MATRADE. There were 12 Malaysian companies participating under the flagship of the Malaysia Rubber Exports Promotion Council (MREPC) with a focus on gloves, condoms and other rubber products.

The Malaysian pavilion was enhanced in order to portray





Malaysia's development as well as reflect its capability of providing high quality products and services to the booming medical devices and healthcare services industry in the region.

The objective of organising the Arab Health Exhibition was to disseminate information in the region of Malaysian-made medicinal value-added products, innovative and affordable hospital aids and equipment and more.

This years' show had huge country pavilions of Germany, the US, UK, Italy, Turkey and UAE representing medical / pharmaceutical companies, hospital furniture & equipment and lots more.

Based on the feedback received from the Malaysian participants, the respond received was better compared to the previous show, with an increased report of sales.

All in all, Malaysian exhibitors need to continue participating in trade fairs such as Arab Health to continually access transnational business, as well as leverage a platform that can provide key information to market access and trends.

BUSINESSUPDATE

DUSSELDORF, **GERMANY**

EDICA is the centre of attraction for all those involved in the healthcare industry. This upcoming event will be held from 12th to 15th November 2014 at the Dusseldorf Exhibition Centre in Dusseldorf, Germany.

Germany is the third largest medical device market in the world, ranking behind USA and Japan. In 2013, the German medical device market was estimated at US\$25.6 billion.



Medica is known to be the largest international medical show that will present advanced technology aided devices which are designed by implementing latest designs and adding in new functionabilities.

The exhibitors will find this show to be the right platform to widen their marketing networks and to promote their range of products to the trade visitors.

Medica Dusseldorf is not only for the promotion of Malaysia medical products but this event also act as an avenue to seek collaboration and contract manufacturing opportunities.

As the size of Malaysian medical devices companies (with the exception of medical gloves companies) is comparatively small, there is a need to collaborate with local and overseas based MNCs and their suppliers to expand the markets and product offerings.



SELIA-TEK STAYS COMPETITIVE AND EFFECTIVE

Ella-TEK Medical Sdn Bhd was established in 2002 as the manufacturing arm of Selia-Tek Sdn Bhd to manufacture and supply medical disposable products and hypodermic needles.

General Manager Mohd Khairi

Mat Isa says Selia-Tek Medical is a modern and effective manufacturer serving customers in different countries and regions worldwide.

"Selia-Tek Medical's current major

medical disposable products are disposable syringes (luer slip syringes), hypodermic needle and IV Catheter which carries the brand name SJ," he said.

Selia-tek also work very closely with local university to develop a medical disposable products and currently had successfully patented two of the products and are moving towards commercialisation.

Selia-Tek Medical is also a pioneer and the only Malaysian company that manufactures hypodermic needles.

"We are also engaged with multinational companies as OEM for their medical products which have received worldwide recognition," said Mohd Khairi.

Selia-Tek Medical's manufacturing philosophy is to achieve uni-



Millim



form quality with the help of the most economical mass-production

technology, harnessed through a dedicated production team, in a harmonious industrial atmosphere.

"Due to our dedication to quality, we have gained several internationally recognised quality certificates and awards. We have been awarded the ISO9001-2008 and ISO13485:2006 certifications," he added.

The company's strength is its strong R&D capabilities and inhouse technology to produce quality medical devices.

"We have a fully functional laboratory. We perform chemical, physical and biological experiments wholly inhouse. Furthermore, we posses ethylene oxide (ETO) sterilising equip-





ment, 10K clean room facilities and 13 sets of plastic injection machines exclusively used for the manufacture of medical products," he said.

These medical devices are higher up in the value chain and already command strong demand in government and private hospitals, both regionally and globally.

"Consequently, we have enlarged our market reach to now include the Middle East, Africa, Europe and Southeast Asia. All the products are marketed through an established national and international distribution network to ensure ready availability and effective customer service support."

EXPORTERS'TRAIL



IGILENZ Medical Devices Sdn Bhd, a wholly owned Malaysian company, was conceptualised and established with the aim of being an alternative supplier of medical and surgical products primarily in Malaysia, and then globally.

From its inception in 2002, the company has grown exponentially from its traditional home base to now cover over 26 countries. Starting with its suture range, Vigilenz today manufactures Hernia Mesh infection control products and other medical disposables.

Chief Executive Officer S Choudhury says the company is looking to draw support from the local health industry towards the company's products.



"With our modern ISO class eight production facilities in Penang, Malaysia, added with highly trained and motivated personnel, we offer unsurpassed quality of

products".

According to Choudhury, Vigile-

nz's mission is to be in the forefront of the manufacture and supply of world class medical and surgical devices and quality services.

It has achieved a few major milestones in the medical and surgical industry, such as ISO13485 accreditation & Class 2A/2B CE accreditation in 2004, taking product liability insurance for all products produced by Vigilenz in 2005 commissioning the first Malaysian-made ETO steriliser in 2005, CE Mark Class 3 (first in Malaysia) and CE Mark Hernia Mesh Class 2B in 2006.

"The reasons for such achievements are hard work and our dedicated local staff," he says.

To date, with its collaboration with MATRADE, Vigilenz has participated in the medical exhibitions of Medica Germany and Arab Health, Dubai.

Choudhury says MATRADE has been proactive with local SMEs by issuing regular information and notifications.

Moving forward, Vigilenz has committed, under the National Key Economic Area (NKEA) healthcare initiative, to spend up to RM25 million in the development of its factory, people, R&D and product portfolio in new product lines in wound management products, while waiting for the offtake agreement from the Ministry of Health.







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