SIRIM PP 18091/05/2013(033524)

SIRIM LINK

Volume 2
2020

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02

UPHOLDING THE QUALITY OF MEDICAL DEVICES

An increase in demand for various medical-related devices and personal protective equipment (PPE) due to the COVID-19 pandemic has shone the spotlight on the importance of ensuring their quality. Playing a central role in upholding this is the Medical Device Authority (MDA) Malaysia.

EXEMPTION FROM REGISTRATION

The Medical Device (Exemption) Order 2016 was gazetted on 18 April 2016 to allow medical device exemptions from registration requirements under Section 5 of Act 737 for numerous purposes, including:

- >> Special Access Medical Devices
- >> Demonstration for marketing
- >> Education
- >> Clinical research or performance evaluation of the medical device(s)
- >> Custom-Made Medical Devices

An importer for or manufacturer of the above is also exempted from having to obtain a licence under subsection 15(1) of the Act. Nevertheless, prior to importing or manufacturing the device, the importer or manufacturer is required to submit a notification to the MDA, and await its acknowledgement, which gives permission for the device to be imported or supplied.

Source: Medical Device Authority

In the nation's battle against COVID-19, items like infrared thermometers, ventilators, face masks and COVID-19 test kits have gained prominence. Due to a sharp rise in demand for the aforementioned items during this time, the Medical Device Authority (MDA) allowed the importation and supply of unregistered medical devices in accordance with the Medical Device (Exemption) Order 2016 to facilitate the nation's efforts in alleviating the spread of the virus. These devices are referred to as Special Access Medical Devices.

"We've seen quite a big jump in the application of or notification for Special Access Medical Devices to be imported and supplied to the Malaysian market. Since the pandemic was declared, we have received almost 800 notifications and over 300 enquiries on this, or around a 10-fold increase compared to normal times," said Ahmad Shariff Hambali, the Chief Executive of MDA.

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PRIORITISING QUALITY

Ascertaining the quality of medical devices is important as these could affect the health and even lives of the users. In this context, quality refers to the safety and performance aspect of the device. The former points to its ability to be used safely to diagnose or treat diseases and injuries as claimed by the manufacturer. Efficacy Performance, on the other hand, refers to if the device is able to perform as claimed.

SERVING MALAYSIA'S MEDICAL DEVICE INDUSTRY

A statutory body under the Ministry of Health Malaysia, the Medical Device Authority (MDA) was established under the Medical Device Act 2012 (Act 738) to serve the country's medical device industry. Its primary responsibility is in controlling and regulating medical devices as well as the industry and related activities in the country. This is done through the implementation and enforcement of the Medical Device Act 2012 (Act 737), which aims to address

public health & safety issues

related to medical devices and facilitate the medical device trade and industry.

To ensure the quality of the device is upheld, it is important to conduct a thorough examination of the evidence that demonstrates the safety of the device and that all associated risks are properly mitigated. To do so, MDA needs to observe all the relevant evidence of the safety and performance of the device including clinical evidence showing that the device is effective as claimed by the manufacturer.

Based on the regulatory framework practiced in Malaysia, MDA looks at documented evidence of a device's performance during the registration process for the device to be supplied in the Malaysia market. The documents would include records of the testing done. Upon being registered, the device is deemed to have undergone all the necessary tests and complied with the relevant standards and regulations.

Nevertheless, performance issues may still arise. Recently, there were numerous observations of the improper reading and recording of the temperatures of patrons at public places, which could, in part, be due to the use of faulty thermometers. According to Ahmad Shariff, incidences may occur from the time the device is manufactured to when it reaches the purchasers and thereafter that could compromise its performance. This is where market surveillance is important.

"This is what we have done with regards to the thermometers. We went to various places and collected a number of thermometers while also enquiring about performance testing conducted to verify the accuracy of the thermometers. Generally, this is one way to ensure the safety, performance and overall quality of the medical devices," he said.

There are many factors that should be taken into consideration to ensure the quality of a medical device from the design stage right up to when it enters the marketplace. During the design stage, for example, it is essential to identify the risks associated with the medical devices and to mitigate them. The risk analysis and management continues throughout the entire production process.

Even once the device is manufactured and placed in the market, there are still challenges along the supply chain. For example, during transportation or storage and even at the user's side, a lot of issues could affect the safety and performance of the medical devices.

"If the risks associated with the particular medical device are not looked into thoroughly at the design stage, it could cause safety issues at the hands of the user later. Similarly, some devices may require special storage, but if this requirement is not met, it could affect their performance," elaborated Ahmad Shariff.

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ENHANCING AWARENESS

Malaysia's medical device industry players can be categorised into three primary groups. The first group tends to have longer histories and more experience in complying with regulatory requirements in various countries.

The second group is typically newer. While they are willing to learn about and comply with the regulations, they may need further guidance. Finally, the third group is comprised of smaller-scale operators who are authorised retailers of medical devices but do not manufacture them.

"The first group tends to have a higher awareness level. They are well-versed, know what is required and are ever ready to comply with the regulations," explained Ahmad Shariff. "This means that we need to create more awareness among the other two groups to ensure that they are on par in terms of awareness level."

Among others, MDA is diligent in engaging regularly with industry players, including manufacturers, distributors and importers. This is done via seminars, workshops, forums and other similar platforms that provide an avenue for them to discuss about the importance of complying with regulations and how they can go about doing that.

"Besides that, it is also important to be able to reach out to the device users and the general public to create better awareness among them as well. One way of doing it is by hosting more seminars for this category of people, especially at public hospitals where we would be able to engage with the relevant medical personnel," continued Ahmad Shariff.

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"In order to position Malaysia as a medical device industry hub, it is essential to help our local manufacturers to reach for a higher level and become global champions. This requires the concerted efforts of all parties – from the manufacturers to the agencies and the government. We also need to ensure that support in terms of finance, expertise, education and regulations, to name a few, needs to be easily available to them."

TAKING ACTION

Before the Medical Device Act 2012 came about, many products were brought into the Malaysian market with unsubstantiated safety and performance claims. Without having enough information at hand, there was a higher risk of the public being misled, which could have caused serious implications to their health and safety.

The implementation of Act 737 allows for the provision of relevant details that will allow the public to make informed choices. They are assured that the medical devices have complied with the relevant safety and performance standards, and have undergone the relevant safety performance tests before they are registered and placed into the market.

In terms of facilitating trade, the Act encourages compliance with regulations, which, in turn, can be akin to having one's foot in the door of the global medical device industry. "When the medical device manufacturers register their products with MDA, it means that they have already adhered to the requirements. This makes it easier for them to meet the requirements set out by other countries, register their products there and ultimately penetrate the global marketplace," said Ahmad Shariff.

"In order to position Malaysia as a medical device industry hub, it is essential to help our local manufacturers to reach for a higher level and become global champions. This requires the concerted efforts of all parties – from the manufacturers to the agencies and the government. We also need to ensure that support in terms of finance, expertise, education and regulations, to name a few, needs to be easily available to them," he declared.

Should the general public encounter any unregistered medical devices or even registered medical devices that they feel are not safe or accurate, they are encouraged to notify MDA at *+603 8230 0300*.

Ahmad Shariff Hambali
Chief Executive of MDA