Malaysian Government to impose restrictions on medical devices business

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The Malaysian Government gazetted the Medical Device (Advertising) Regulations 2019 ('Advertising Regulations') and the Medical Device (Duties and Obligations of Establishments) Regulations 2019 ('Establishments Regulations') on 15 November 2019. Both sets of subsidiary legislation will come into operation on **1 July 2020**.

Terminology

The expressions 'medical device' and 'establishment' are defined in the Medical Device Act 2012 ('Act') as follows –

*"'"**medical device**" means—*

(a) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of -

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;

(iv) support or sustaining life;

(v) control of conception;

(vi) disinfection of medical device; or

(vii) providing information for medical or diagnostic purpose by means of in-vitro examination of specimens derived from the human body,

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

(b) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the Gazette;"

*""'"**establishment**" means -*

(a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and

(b) an authorised representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorised representative being —

(A) a person domiciled or resident in Malaysia; or

(B) a firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia."

The following is a summary of the salient matters in the said subsidiary legislation –

The Advertising Regulations

The Advertising Regulations –

(1) prohibit a person from advertising any registered medical device without the approval of the Medical Device Authority ('Authority');

(2) sets out the documents and fees to be included in an application to the Authority for approval to advertise a registered medical product; and

(3) requires an advertisement that advertises a registered medical product to include a statement that the medical device is registered under the Act and the registration number assigned to the registered medical device by the Authority.

The Establishments Regulations

The Establishment Regulations imposes the following obligations on an establishment to –

(1) maintain distribution records;

(2) maintain a record of the handling of complaints;

(3) undertake mandatory reporting of incidents;

(4) notify the Authority of any field corrective or preventive action;

(5) comply with procedures for voluntary recall; and

(6) to comply with mandatory recall required by the Authority.

Distribution records

The Establishment Regulations requires an establishment to maintain a distribution record in respect of each medical device manufactured, imported, exported and placed in the market that contains the following information –

(a) the details of the consignee of the medical device;

(b) the detailed specifications of the medical device;

(c) the address of the place of storage of the medical device;

(d) the details of the delivery and receipt of the medical device;

(e) the details about the disposal of the medical device; and

(f) any other details as may be required by the Authority.

In the case of an implantable medical device, the Establishment Regulations also require the distribution record to contain the following additional information –

(a) the details of the healthcare facility where the implantable medical device is implanted;

(b) the details of the patient on whom the implantable medical device is implanted or used;

(c) the date of implantation of the medical device; and

(d) the details of the removal of the implantable medical device, if applicable.

An establishment is required to maintain a distribution record for the following periods –

(a) two years after the medical device is placed in the market;

(b) if the medical record is for export, for two years from the date that the medical device is shipped out of Malaysia; or

(c) if the medical device has a projected useful shelf life, for the projected useful shelf life of the medical device as determined by the manufacturer.

Records of a complaint handling

An establishment is required to ensure that a record of a complaint handling contains a procedure relating to –

(a) an assessment of a complaint;

(b) an investigation carried out by the establishment;

(c) the corrective and preventive actions taken by the establishment;

(d) a communication with the complainant; and

(e) maintenance of record.

The records on a complaint relating to a medical device is required to include the following information –

(a) the details of the medical device;

(b) the details of the complaint;

(c) the description of the complaint and the incident including the history of the incident; and

(d) any other records or information to assist the investigation of the incident.

The records on complaint is to be kept for five years, in addition to the projected useful life of the medical device as determined by the manufacturer.

Mandatory problem reporting

Subject to the exception in regulation 5(7) of the Establishment Regulations, regulation 5(1) requires an establishment to submit a mandatory report under section 40(1) of the Act (which imposes mandatory reporting obligations on the establishment in the event of specified serious incidents) to the Authority relating to any incident that comes to the establishment's attention occurring within or outside Malaysia.

In addition to the above, the establishment is required to investigate and if necessary, conduct a field corrective action to prevent a recurrence of the incident. The establishment must submit an investigation report to the Authority within 30 days from the date of submission of the mandatory report under regulation 5(1) of the Establishment Regulations or within any extension of time granted by the Authority.

If the Authority is satisfied with the action taken as reported in the investigation report, the Authority may close the matter and notify the establishment in writing of its decision. If the Authority is not satisfied with the action taken, as reported in the investigation report, it may –

(a) order the establishment to carry out further investigation and submit a revised investigation report;

(b) order the establishment to recall the medical device;

(c) cancel the medical device registration; or

(d) suspend or revoke the establishment licence.

Regulation 5(7) of the Establishment Regulations provides that the requirement to submit a mandatory report does not apply to an incident occurring outside Malaysia if that incident has been reported by the establishment to the regulatory agency of the country in which the incident occurred and a field corrective action has been taken by the manufacturer or the establishment.

Field corrective or preventive action

An establishment may, at any time, undertake a field corrective or preventive action, and shall notify the Authority before undertaking such action.

The establishment is required to submit to the Authority a report (in such form as may be determined by the Authority) of the field corrective or preventive action after the completion of the field corrective or preventive action.

If the Authority is satisfied with the field corrective or preventive action taken by the establishment, the Authority may close the matter and notify the establishment in writing of its decision. If the Authority is not satisfied with the field corrective or preventive action taken, it may–

(a) order the establishment to take further action to ensure the safety and performance of the medical device;

(b) order the establishment to recall the medical device;

(c) cancel the medical device registration; or

(d) suspend or revoke the establishment licence.

Voluntary recall

Before undertaking a voluntary recall of a medical device, an establishment must notify the Authority and all persons affected by the recall of the medical device within the following time frames –

(a) for a class I recall, not less than 48 hours before the recall is made;

(b) for a class II recall, not less than three days before the recall is made; and

(c) for a class III recall, not less than five days before the recall is made.

Each class of recall is defined in regulation 7(1) of the Establishment Regulations. Among other factors, a class I recall being a high risk situation, a class II recall being a medium risk situation and a class III recall being a low risk situation.

The establishment is required to submit to the Authority a report (in such manner as may be determined by the Authority) within 30 days after the completion of a voluntary recall of the medical

device. The Authority may, after its receipt of the report, request the establishment to provide other additional information, particulars or documents within the time stipulated in the request.

If the Authority is satisfied with the report and any further information requested by the Authority, it may close the matter and notify the establishment in writing of its decision. If the Authority is not satisfied with the voluntary recall of a medical device undertaken by an establishment, it may–

(a) order the establishment to take any other necessary action to ensure that the medical device is not available in the market;

(b) cancel the medical device registration; or

(c) suspend or revoke the establishment licence.

The Establishment Regulations authorise the Authority to publish the information of the voluntary recall of a medical device to the public.

Mandatory recall

The Authority may, in writing, order an establishment to recall any medical device at any time due to patient safety and public health.

Upon a mandatory recall order being issued, the establishment is required to undertake the recall of the medical device and report the result of the recall within the period determined by the Authority.

If the Authority is satisfied with the report of the mandatory recall, it may close the matter and notify the establishment in writing of its decision. If the Authority is not satisfied with the report of the mandatory recall, it may–

(a) order the establishment to take any other action to ensure that the medical device is not available in the market;

(b) cancel the medical device registration; or

(c) suspend or revoke the establishment licence.

The Establishment Regulations authorise the Authority to publish the information of the voluntary recall of a medical device to the public.

Comments

The Advertising Regulations and the Establishment Regulations will tighten up the operating environment for manufacturers, importers, exporters and distributors of medical devices in Malaysia. The period for which distribution records are required to be maintained should be extended as these records will assist in the conduct of field corrective or preventive action, voluntary recalls and mandatory recalls. That aside, both sets of regulations are to be welcomed in the interest of protecting the safety of users of medical devices.