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DRAFT MEDICAL DEVICE GUIDANCE DOCUMENT

POST MARKET SURVEILLANCE REGULATORY AUDIT FOR MEDICAL DEVICE MANUFACTURERS

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012; and

c) Medical Device Regulations 2015.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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POST-MARKET SURVEILLANCE REGULATORY AUDIT FOR MEDICAL DEVICE MANUFACTURERS

1. Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices in the Malaysian market meet Medical Device Act 2012 (Act 737) and its regulations for safety, quality, performance and effectiveness, and that they are used safely.

Post market surveillance regulatory auditing is one of the activities undertaken by the Medical Device Authority to ensure effective control of medical devices.

2. Scope

This document specifies the requirements for post market surveillance regulatory audit on manufacturers of medical devices.

Medical device is defined in MDA/GD-01: Guidance Document on Definition of Medical Device, including those used for the *in vitro* examination of specimens derived from the human body.

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 Manufacturer

As specified in **Section 2** of Act 737.

3.2 Regulatory officer

Officer of the Medical Device Authority as specified in **Section 17** of Act 738.

3.3 Major non-compliance

A major non-compliance is where the relevant requirements of Medical Device Act 2012 and Medical Device Regulations or any other requirement specified by the authority have not been (appropriately) applied and/or which may result in a significant risk to public health, led to the death or serious deterioration in the state of health of a patient, user or other person.

3.4 Minor non-compliance

A Minor non-compliance is where the relevant requirements of Medical Device Act 2012 and Medical Device Regulations or any other requirement specified

by the authority have not been (appropriately) applied. The severity of a risk of a minor non-compliance would be significantly less than a major non-compliance.

4. Post-market surveillance regulatory audit

4.1 Post-market surveillance regulatory audit is carried out by either:

a) Proactive surveillance; or

b) 'For cause' audit.

Proactive surveillance audit is carried out dependant on what the authority deems appropriate e.g. targeted audits in relation to a specific category. A '**for cause'** audit is conducted as a result of a market issue, which requires market follow-up in the interest of public health.

4.2 Post-market surveillance regulatory audits can be initiated from a number of sources:

a) concerns arising in relation to vigilance issues;

b) changes in legislation;

c) complaints received about marketed products;

d) post-market surveillance sampling across a specific technology/ sector;

e) receipt of information from internal/ external sources;

f) requests from other Regulatory Authorities; or

g) any other source that may arise from time to time.

This is not an exhaustive list but should serve to outline how post-market surveillance regulatory audits are chosen.

Post-market surveillance can take place by way of regulatory audit. The aim of the regulatory audit is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of the medical device regulation and related statutory requirements.

An audit by the authority does not mean that there has been a breach of the legislation. It may be part of a proactive programme of surveillance deemed necessary by the authority.

5. Regulatory officers and information for inspection

An officer of the authority may visit manufacturing premises to conduct a post-market surveillance regulatory audit.

6. Before the regulatory audit

The authority will contact the medical device manufacturer to arrange the date, time and duration of the audit. In the case of a proactive audit, the manufacturer will be given at least two weeks' notice prior to the audit.

A confirmation letter will be sent to the medical device manufacturer specifying the date and time agreed and a list of the areas the audit will cover.

The manufacturer may be requested to supply some information in advance of the audit, for example:

a) a brief company profile;

b) a list of products manufactured;

c) the details of the Conformity Assessment Body;

d) a high level manufacturing flow chart; and

e) relevant procedures.

As 'for cause' audits, generally the need will arise from a public health issue. The authority is obliged to investigate an issue by whatever method appropriate. In this case, a request to carry out onsite audit immediately may be made. The date of the visit will only be changed in exceptional circumstances.

7. During the audit

At the start of the audit, a brief opening meeting will take place to outline the audit, explain the requirements under the legislation and discuss the audit plan, the types of non-compliances, etc.

The regulatory officer will take note of any areas of concern and discuss these when they arise with the manufacturer during the audit.

At the end of the audit, a close out meeting will be held where the findings of the audit will be presented and any non-compliance will be raised. At this meeting, the non-compliances will be documented and discussed and a timeframe for completion of a corrective action plan will be agreed with the medical device manufacturer.

Once satisfactory responses have been received, the authority will issue a letter to the medical device manufacturer to that effect.

Where satisfactory responses have not been received and/or where breaches of the regulations have taken place, further action may be taken which can, in certain circumstances involve the use of the enforcement power by the authority as outlined in the act and regulations.

8. Non-compliances

There are two types of non-compliances; major and minor non-compliances.

If it is the case that there is a major non-compliance, the manufacturer will be required to respond to the non-compliance with the corrective action(s) within a short timeframe as agreed by the authority. There will also be an agreed timeline for the correction of a minor non-compliance. Evidence of completed corrective action(s) shall be supplied to authority.

In addition, there may be observation(s) raised in an audit. An observation is a mechanism to prompt the manufacturer to improve future practice and does not require corrective action. However, observation will be discussed and where possible a process of implementation will be provided and agreed upon by the authority.

MEDICAL DEVICE AUTHORITY

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