POST MARKETING SURVEILLANCE PLAN

Medical Devices Regulatory Division

National Medicines Regulatory Authority

Sri Lanka

Introduction

A precondition for placing a product on the market is that conformity to the relevant Essential Requirements, including a favorable benefit/risk ratio, has been demonstrated. The extent of the data that can be gathered in the pre-market phase does not necessarily enable the manufacturer to detect rare complications or problems that only become apparent after wide-spread or long-term use of the device. As part of the manufacturer's quality system, an appropriate post-market surveillance plan is a key to identifying and investigating residual risks associated with the use of medical devices placed on the market. These residual risks should be investigated and assessed in the post-market phase through systematic Post-Market Surveillance study (ies). PMS studies are one of important parameter for risk management process.

Scope

The objective of this document is to provide guidance on the appropriate use and conduct of PMS studies to address issues linked to residual risks. The intention is not to impose new regulatory requirements. Post Marketing Clinical Follow-up (PMCF) studies are an important element to be considered in PMCF or PMS plans. The principles for PMCF studies set out in this guidance are not intended to replace PMCF or PMS plans. They are or may be applicable to PMCF studies conducted for other purposes.

This has to confirm clinical performance and safety throughout the expected lifetime of the medical device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

Method

Post market surveillance plan shall address the collection and utilization of available information, in particular:

- information concerning serious incidents, including information from **Periodic Safety Update Reports – PSURs**, and field safety corrective actions;
- records referring to non-serious incidents and data on any undesirable side-effects;
- information from trend reporting (a reporting type used by the manufacturer when a significant increase in events not normally considered to be incidents occurred and for which pre-defined trigger levels are used to determine the threshold for reporting); relevant specialist or technical literature, databases and/or registers;
- information, including feedbacks and complaints, provided by users, distributors and importers;
- and publicly available information about similar medical devices.

The post market surveillance plan shall cover at least:

- a proactive and systematic process to collect any required information. The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;
- effective and appropriate methods and processes to assess the collected data;
- suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit- risk analysis and of the risk management;
- effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field;
- methods and protocols to manage the events subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

- methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
- reference to procedures to fulfil the manufacturers obligations for PMS system,
- systematic procedures to identify and initiate appropriate measures including corrective actions;
- effective tools to trace and identify devices for which corrective actions might be necessary;

Annex I

MEDICAL DEVICE REPORT FORM
Medical Divice vigilance system
National Medicines Regulatory Athority
Sri Lanka

1. Administrative information
Recipient Name of National Competent Authority **National Medicines Regulatory Authority – Sri Lanka**
Address of National Competent Authority **No : 120, Norris Canal Road, Colombo 10, Sri Lanka**
Date of this report
Reference number assigned by the manufacturer
Reference number assigned by NMRA
Type of report ☐ Initial report ☐ Follow-up report ☐ Combined Initial and Final report ☐ Final report
Does the incident represent a serious public health threat? ☐ Yes ☐ No
Classification of incident ☐ Death ☐ Unanticipated serious deterioration in state of health ☐ All other reportable incidents
Identify to what other Regulatory Agencies this report was also sent:

2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☐ Authorised Representative ☐ Others (identify the role):	
i. Manufacturer information	
Name	
Contact person name	
Address	
Postal code	City
Phone	Fax
E-mail	Country
ii. Authorised Representative information	
Name	
Contact person name	
Address	
Postal code	City
Phone	Fax
E-mail	Country
iii. Submitter's information (if different from section 3 or 4)	
Name	
Contact person name	
Address	
Postal code	City
Phone	Fax
E-mail	Country

3. Medical device information	
Classification ☐ Class I ☐ Class II A ☐ Class II B ☐ Class III ☐ Active implantable device ☐ IVD Class A ☐ IVD Class B ☐ IVD Class C ☐ IVD Class D ☐ Other IVD device	
Nomenclature system (preferable GMDN)	Nomenclature code
Nomenclature text	
Commercial name / brand name	
Model number	Catalogue number
Serial number(s) (if applicable)	Lot / batch number(s) (if applicable)
Software version number (if applicable)	
Device Manufacturing date	Expiry date
Implant date (for implants only)	Explant date (for implants only)
Duration of implantation (to be filled is the exact implant or explant dates are known)	
Accessories / associated device (if applicable)	
Notified Body (NB) ID-number	
4. Incident information	
User facility report reference number (if applicable)	
Manufacturers awareness date	
Date the incident occurred	
Incident description narrative	
Number of patients involved (if known)	Number of medical devices involved (if known)

Medical device current location / disposition (if known)

Operator of the medical device at the time of incident (select one)

☐ health care professional ☐ patient

☐ other

Usage of the medical device (indicate)

☐ initial use

☐ reuse of a single use medical device

☐ reuse of a reusable medical device

☐ re-serviced / refurbished

☐ problem noted prior use

☐ other (please specify)

5.Patient information

Patient outcome.

Remedial action taken by the healthcare facility relevant to the care of the patient.

Age of the patient at the time of incident (if applicable)

Gender (if applicable)

☐ Female ☐ Male

Weight in kilograms (if applicable)

6.Healthcare facility information

Name

Contact person within the facility

Address

Postcode	City
Phone	Fax
E-mail	Country

7.Manufacturer's preliminary comments (Initial / Follow-up report)
Manufacturer's preliminary analysis.
Initial corrective actions / preventive actions implemented by the manufacturer:
Expected date of next report:
8.Results of manufacturers final investigation (Final report)
The manufacturer's device analysis results.
Remedial action / corrective action / preventive action / Field Safety Corrective Action: *NOTE: In the case of a FSCA the submitter needs to send Field Safety Notice*
Time schedule for the implementation of the identified actions:
Final comments from the manufacturer:
Further investigations:
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause? ☐ Yes ☐ No
If yes, number of similar incidents:
If yes, indicate in which countries and the report reference numbers of the incidents:
For Final Report only. The medical device has been distributed to the following countries: USA – UK - Australia – Japan – Malaysia – Denmark – New Zealand –

Canada – Germany - Other country (please specify):
3. Comments:
_____ Signature _____ _____ Name Position

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the National Medicines Regulatory Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.