GHWP/WG4/PD002:2024

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: **Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative**

Authoring Group(s): **Work Group 4: Post-Market**

Date: June 2024

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1. Preface

This revised guidance on adverse event reporting for Percutaneous Coronary Intervention (PCI) devices is developed under the Work Group 4 of Global Harmonization Working Party (GHWP) to promoting the alignment of regulatory standards and establishing a global framework for regulating medical devices across regulatory authorities and industries. This guidance aims to foster the exchange of information and best practices among members to accelerate the harmonization of medical device regulations and enhance patient safety. Through collaboration and shared knowledge, the GHWP strives to create a coordinated approach that safeguards public health and ensures the timely reporting and evaluation of adverse events related to medical devices.

2. Introduction

2.1 This document is to adopt the former Asian Harmonization Working Party (AHWP) guidance document *AHWP/WG4/F001:2016 Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representatives* due to the change of organization name. In addition to the review of suitability for current practices, references and requirements.

3. Purpose

3.1 This document is to supplement and read in conjunction to the latest Global Harmonization Working Party (GHWP) guidance document *GHWP/WG4/P002:2024 Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives*.

3.2 Examples are given to distinguish reportable adverse events (RAEs) and non-reportable adverse events (NRAEs) in general.

4. Scope

4.1 This guidance document applies to adverse event (AE) reporting of PCI devices.

5. References

5.1 Work Group 4 of the Global Harmonization Working Party (2024). *Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives (GHWP/WG4/P001:2024)*

5.2 Work Group 4 of the Global Harmonization Working Party (2023). *Post Market Resources Center (GHWP/WG4/F001:2023)*

5.3 Medical Device Coordination Group (MDCG) Document “DSVG 01 – Devices for Cardiac Ablation”

5.4 Medical Device Coordination Group (MDCG) Document “DSVG 02 – Coronary Stents and associated delivery systems”.

6. Definitions

6.1 **Percutaneous Coronary Intervention (PCI) devices** are used to relieve the narrowing or occlusion of obstructive coronary artery disease with nonsurgical technique through percutaneous methods (commonly through femoral or radical arteries) e.g. coronary stents, balloons, guide wires

7. Examples of Reportable Adverse Events and Non-Reportable Adverse Events for PCI devices

7.1 **Table 1** and **Table 2** present examples of reportable adverse events (RAEs), non-reportable adverse events (NRAEs) and trend reporting of adverse events for PCI devices. To distinguish RAEs, NRAEs and trend reporting, these examples should be reviewed in conjunction with the GHWP guidance document *GHWP/WG4/P002:2024 Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives* for further details before making decisions. Additional examples applicable in European Union could be found at the latest Medical Device Coordination Group (MDCG) Document "*DSVG 01 – Devices for Cardiac Ablation*" and "*DSVG 02 – Coronary Stents and associated delivery systems*".

Table 1 Examples of RAEs and NRAEs for PCI devices

Reportable Adverse Events (RAEs)	Non-report adverse Events (NRAEs)
1. Death or heart failure that is probably or possibly device-related	1. Death or heart failure if there is evidence that it is not device-related
2. Cardiac tamponade (pericardial effusion) or cardiogenic shock	2. Haematoma at the vascular access site
3. Creation of distal air embolus	3. Hypotension or hypertension stated in the IFU
4. Difficulty deflating the balloon or other delivery system or withdrawal complications	4. Fever or infection or pain at insertion site stated in the IFU
5. Difficulty advancing the stent or crossing the lesion, not associated to procedural or patient factor	5. Pseudoaneurysm stated in the IFU and not due to malfunction of the device.
6. Acute/ sub-acute stroke/ cerebrovascular accident	6. Side branch occlusion
7. Balloon rupture (if used within rated burst pressure).	7. Distal emboli (tissue, thrombotic/ thrombus, plaque)
8. Adverse reaction associated with the stent material and/ or delivery system materials, drug or polymer carrier if the reaction is not identified in the IFU	8. Acute arterial perforation/ rupture/ dissection, not associated to malfunction of the device
9. Thromotic/ calcific occlusion or stenosis (in-stent and target vessel) or myocardial infarction (suspected to be stent-related)	9. Arrhythmias, including atrial and ventricular
10. Incomplete stent apposition/ expansion (malposition) or excessive recoil	10. Angina pectoris
11. Coronary or stent embolism	11. Non-fatal bleeding complications, which may require transfusion/ haemorrhage
12. In vivo stent damage or deformation or device fragmentation or device fragment emboli migration	12. Coronary artery spasm
13. Product defect, except those identified by the user prior to use, such as device deformation (e.g. kink, bent, flare strut, break, twisted etc.), packaging compromised, foreign material, labelling issue and etc.	13. Premature stent dislodgement with or without migration
14. Unanticipated serious injury	14. Difficulty advancing the stent or crossing the lesion, linked to procedural or patient factor
	15. Infection – local and/ or systemic
	16. Peripheral vascular or nerve injury

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Table 2 Examples of NRAEs for PCI devices require trend reporting

The following NRAEs should be reported when there is a <u>significant increase in the rate</u> of AEs identified
1. Side branch occlusion
2. Distal emboli (tissue, thrombotic/ thrombus, plaque)
3. Acute arterial perforation/ rupture/ dissection, not associated to malfunction of the device
4. Arrhythmias, including atrial and ventricular
5. Angina pectoris
6. Non-fatal bleeding complications, which may require transfusion/ haemorrhage
7. Coronary artery spasm
8. Premature stent dislodgement with or without migration
9. Difficulty advancing the stent or crossing the lesion, linked to procedural or patient factor
10. Infection – local and/ or systemic
11. Peripheral vascular or nerve injury

8. Points to Consider for Reportable Adverse Events

8.1 RAEs must be promptly reported to the relevant regulatory authorities (RAs) within the specified timeframe, and RAE reports should be submitted in accordance with their requirements. A list of post-market contact information for RAs can be accessed at the Post Market Resource Center (PMRC) maintained by GHWP Work Group 4. For detailed guidance on the RAEs reporting procedure, please refer to the GHWP guidance document *GHWP/WG4/P002:2024 Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives*.