GHWP/WG4/PFD002:2024

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED FINAL 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**

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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), based on the previous guidance document, **Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative (AHWP/WG4/F001:2016)** 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 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 **Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representatives (AHWP/WG4/F001:2016)** 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 be read in conjunction with the latest Global Harmonization Working Party (GHWP) guidance document **Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives (GHWP/WG4/PD001:2024)**.

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

4. Scope

4.1 This guidance document applies to 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/PD001:2024)***

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

5.3 European Commission (2024). ***Medical Devices MDCG 2024-1-1 Guidance on the vigilance system for CE-marked devices DSVG 01 Devices for Cardiac Ablation***

5.4 European Commission (2024). ***Medical Devices MDCG 2024-1-2 Guidance on the vigilance system for CE-marked devices 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 techniques through percutaneous methods (commonly through femoral or radial 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 AEs, non-reportable AEs and trend reporting of AEs for PCI devices. To distinguish reportable AEs, non-reportable AEs and those required trend reporting, these examples should be reviewed in conjunction with the GHWP guidance document **Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives (GHWP/WG4/PD001:2024)** for further details before making decisions. Additional examples applicable in European Union could be found at the latest European Commission 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 Reportable AEs and Non-reportable AEs for PCI devices

Reportable Adverse Events	Non-reportable Adverse Events
1. Death or heart failure that is probably or possibly device-related 2. Cardiac tamponade (pericardial effusion) or cardiogenic shock 3. Creation of distal air embolus 4. Difficulty deflating the balloon or other delivery system or withdrawal complications 5. Difficulty advancing the stent or crossing the lesion, not associated to procedural or patient factor 6. Acute/ sub-acute stroke/ cerebrovascular accident 7. Balloon rupture (if used within rated burst pressure) 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 9. Thromotic/ calcific occlusion or stenosis (in-stent and target vessel) or myocardial infarction (suspected to be stent-related) 10. Incomplete stent apposition/ expansion (malposition) or excessive recoil 11. Coronary or stent embolism 12. In vivo stent damage or deformation or device fragmentation or device fragment emboli migration 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. 14. Unanticipated serious injury	1. Death or heart failure if there is evidence that it is not device-related 2. Haematoma at the vascular access site 3. Hypotension or hypertension stated in the IFU 4. Fever or infection or pain at insertion site stated in the IFU 5. Pseudoaneurysm stated in the IFU and not due to malfunction of the device 6. Side branch occlusion 7. Distal emboli (tissue, thrombotic/ thrombus, plaque) 8. Acute arterial perforation/ rupture/ dissection, not associated to malfunction of the device 9. Arrhythmias, including atrial and ventricular 10. Angina pectoris 11. Non-fatal bleeding complications, which may require transfusion/ haemorrhage 12. Coronary artery spasm 13. Premature stent dislodgement with or without migration 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

Table 2 Examples of Non-reportable AEs for PCI devices require trend reporting

The following Non-reportable AEs should be reported when there is a significant increase in the rate[#] 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

Note: [#]*Please refer to Section 10 of Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives (GHWP/WG4/PD001:2024) for details*

8. Points to Consider for Reportable Adverse Events

8.1 Reportable AEs must be promptly reported to the applicable regulatory authorities (RAs) in each jurisdiction where the event has occurred or where the device is marketed according the applicable requirements in each jurisdiction within the specified timeframe, and the AE 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 WG4. For detailed guidance on the AEs reporting procedure, please refer to the GHWP guidance document **Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives (GHWP/WG4/PFD001:2024).**