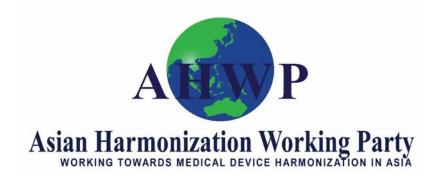
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PROPOSED FINAL DOCUMENT

Title: Guidelines for Adverse Event Reporting of

Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized

Representative

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Guidelines for adverse event reporting of Percutaneous Coronary Intervention (PCI) devices¹ for the Medical Device Manufacturer or its Authorized Representative

To be read in conjunction with the AHWP adverse event reporting guidance of ref.

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

AHWP/WG4/F001:2015

- ¹ PCI (Percutaneous coronary intervention) devices they are used in treating obstructive coronary artery disease with nonsurgical technique through percutaneous methods (commonly through femoral or radial arteries) e.g. coronary stents, balloons, guide wires
- ² Reportable adverse events must be reported to the relevant regulatory authority (ies) within the required timeframe. Please refer to the AHWP guidance document of ref. AHWP/WG4/F001:2015 for details
- ³ Non-reportable events shall be reported when an adverse trend is identified