Guidance for manufacturers on reporting adverse incidents involving Artificial Heart Valves under the vigilance system

To be read in conjunction with the guidelines on a medical devices vigilance system MEDDEV 2.12/1

Biological / mechanical – surgical heart valves

Report as individual events (in line with MEDDEV timescales)
• Death or heart failure that is probably or possibly device-related • Explantation – possible or definite device failure • Leaflet rupture / perforation / tearing / detachment from stent posts • Occluder fracture or escape • Fracture of the stent or valve structure • Separation of sewing cuff from housing or stent • Prosthesis thrombosis • Valve contamination • Embolisation or migration of whole or part of the heart valve • Incidents relating to accessories or instrument failure

Reportable as periodic summary reports (PSR)*	
	Periodicity
Valvular regurgitation or leak (central / peri / para / unknown aetiology)	3 monthly
Explantation within 24hrs following implantation	3 monthly
Stroke (TIA / CVA), permanent neurological deficit (paralysis)	3 monthly
Explantation - no common cause - within device life expectancy	6 monthly
Intrinsic / extrinsic mineralization (calcification) within 7 years of implantation	6 monthly
Structural deterioration causing stenosis (no common cause) within 7 years of implantation	6 monthly
Non-structural dysfunction (eg leaflet obstruction / entrapment by pannus in growth, suture/tissue dehiscence)	Annually

Reportable at the time the adverse trend is identified
• Cardiac arrhythmias • Endocarditis • Fibrosis • Valve distortion (eg inappropriate sizing) • Haemolysis / haemolytic anaemia • Haemorrhage, anticoagulation or antiplatelet-related event • Infection – other than endocarditis • Myocardial infarction • Overall mortality rate of valve population • Angina

Specific additional guidance for transcatheter heart valves (THV)

Report as individual events (in line with MEDDEV timescales)
Delivery system failure / complications
Accidental vessel perforation with pericardial effusion or cardiac tamponade

Reportable as periodic summary reports (PSR)*	
Accidental vessel perforation without pericardial effusion or cardiac tamponade	6 monthly
Conduction system injury	6 monthly

Reportable at the time the adverse trend is identified
Complications linked with a transapical cardiac incision or balloon aortic valvuloplasty
Access site haematoma or inflammation
Improper implantation location (potentially causing coronary flow obstruction or mitral valve impairment or damage)

*** If you can't use PSR, then report these events individually.**