Guidance for manufacturers on reporting adverse incidents involving Intraocular Lenses under the vigilance system

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

Report as individual incidents
(in line with MEDDEV timescales)

Clinical / Symptomatic

- Lens opacification
- Lens explantation due to
  - Decrease in best corrected visual acuity
  - Significant halos/glare/starbursts
  - Significant induced irregular astigmatism
  - Diplopia, or other significant visual disturbance
  - Lens discoloration
  - lens defect
- Endophthalmitis
- Early cataract formation subsequent to phakic IOL implantation
- Intraocular haemorrhage
- Unexplained poor visual outcome as determined by the clinician

Can be included in periodic summary reports (PSR)**

Clinical / Symptomatic	**Periodicity**
• IOL induced iritis	
• Post operative secondary glaucoma	
Device	
• Use errors resulting in serious injury and not falling into any identified category	

Report at the time the adverse trend is identified

- All reportable adverse incidents***

Clinical / Symptomatic

- Posterior capsular opacification
- Posterior capsular tear

Device • Fracture of detachment of the haptic • Incorrect labelling or lens, including lens power • Failure of lens injectors		

***If in an incident appears to meet criteria contained in more than one column, ensure it is included in submissions under each reporting format, even if this results in duplication of reporting for that incident.**
**** If you can't use PSR, then report these events individually.**
***** Until the new MIR form, which includes similar incident data, is adopted, trend reports should be submitted for reportable events, in line with the requirements of MEDDEV 2.1**