

# APPENDIX 5

## ASR timelines

### Department of Health and Ageing Answer to Question on Notice

Early 2004	TGA approves ASR Resurfacing
Early 2005	TGA approves ASR XL
Oct 2006	2006 National Joint Replacement Registry (NJRR) annual report released: Mentions ASR Resurfacing but the difference in revision rates is noted in the report as not significant
June 2007	Orthopaedic Expert Working Group (OEWG) established to review NJRR data
Aug 2007	OEWG meets for the first time – ASR NOT discussed because it had not been identified as an implant of concern at that stage
Sept 2007	J&J discuss ASR Resurfacing revision rates with TGA J&J agreed to restrict supply to surgeons who undergo further training, and to issue a Safety Notice to all implanting surgeons advising them of the revision rates and J&J intention to supply only to specially trained surgeons
Oct 2007	2007 NJRR annual report released Identifies ASR Resurfacing as an implant that is experiencing higher than expected revision rates
Oct 2007	TGA notifies other regulatory agencies TGA notifies other regulatory agencies of J&J's intended actions regarding ASR Resurfacing in the Australian market through a process called National Competent Authority Reporting (NCAR)
May 2008	J&J provides status report J&J provides update on status of actions agreed in Sept 2007. Safety Notice sent – as a result of supply being conditional on re-training, 15 surgeons had abandoned the implant, another 16 said that they would continue to use it. Overall use dropped dramatically
May 2008	TGA refers ASR Resurfacing issue to OEWG at its May meeting ASR Resurfacing, including J&J/TGA actions taken in Sept 2007 referred to OEWG for comment and/or endorsement. OEWG endorses actions taken and recommends that monitoring of the implant continue
June 2008	OEWG meets once again No change to position regarding ASR Resurfacing
Sept 2008	Internal review of TGA process begins Following concerns over procedural fairness afforded by the TGA process being used to investigate implants identified as having higher than expected revision rates by the NJRR, TGA initiates an internal review of that process

Oct 2008	2008 NJRR annual report released Re-identifies ASR Resurfacing as having high revision rates. Identifies that the ASR XL acetabular cup has higher than expected revision rates <u>ONLY</u> when used in conjunction with the Corail femoral stem component
July 2009	Internal review of TGA process ends The review found that the process is fair and appropriate and was resumed – Implants that were identified for the first time in the 2008 NJRR annual report were processed in 2009
Aug 2009	Out of Session Briefing provided to OEWG The briefing provided the OEWG a status on the process of consideration of implants identified as having high revision rates in the NJRR reports – with a view to restarting the process
Oct 2009	2009 NJRR annual report released Re-identifies ASR Resurfacing as having high revision rates. Identifies that the ASR XL acetabular has higher than expected revision regardless of which femoral stem component is used
Oct 2009	TGA and J&J have further discussions about ASR TGA indicated that in light of the information in the 2009 NJRR report, J&J would be expected to justify on-going supply of the implant. J&J indicated that ASR sales had reduced dramatically, and that there was on-going concern about the implant. This was making the implant unviable so J&J would be withdrawing the implant from the Australian Market however requests that some components be allowed to remain for partial revision purposes
Dec 2009	OEWG meeting includes discussion on ASR XL implant OEWG endorses the actions taken by J&J and the TGA also endorses the request to allow some components to remain available
Dec 2009	ASR Resurfacing and ASR XL removed from the market
Feb 2010	6 <sup>th</sup> Meeting of OEWG ASR issue had already been dealt with – no discussion on ASR
June 2010	7 <sup>th</sup> Meeting of OEWG Discussion about Metal on Metal (MoM) hip implants like the ASR. OEWG advised that there should not be a blanket condemnation of MoM implants – also advised against routine analysis of blood samples for Cobalt and Chromium levels as an indicator of early implant failure
Aug 2010	Worldwide recall of ASR implants
Oct 2010	2009 NJRR annual report released Re-identifies ASR Resurfacing and ASR XL as having high revision rates
Nov 2010	8 <sup>th</sup> Meeting of OEWG Action on ASR complete – the committee considered other implants
Mar 2011	9 <sup>th</sup> Meeting of OEWG Action on ASR complete – the committee considered other implants
May 2011	10 <sup>th</sup> Meeting of OEWG Further discussions on concerns regarding MoM implants. OEWG re-affirmed the recommendations provided at its 7 <sup>th</sup> meeting in June 2010
June 2011	11 <sup>th</sup> Meeting of OEWG Action on ASR complete – the committee considered other implants