

**July 2007 PBAC OUTCOMES – Subsequent decision to defer**

| DRUG AND FORM  | DRUG USE AND TYPE      | LISTING REQUESTED BY SPONSOR   | PBAC OUTCOME AND COMMENT  |
|--|------------------------|--|---|
| <p>DOCETAXEL, vial, 20 mg, 80 mg, Taxotere®</p> <p>sanofi-aventis Australia Pty Ltd<br/>Major submission</p> | <p>Prostate cancer</p> | <p>Authority required <i>for treatment of androgen independent (hormone refractory) prostate cancer.</i></p> | <p>The PBAC noted that no new efficacy and safety data had been presented, but that a new Australian Utility study had been conducted to elicit utility weights for a new Q-TWiST analysis. Although there were some residual concerns with the Q-TWiST analysis, the PBAC concluded that it was unlikely that further adjustments would alter substantially the resultant incremental cost-effectiveness ratio (ICER).</p> <p>Nevertheless, the PBAC considered that the ICER was unacceptably high. The Committee indicated that, if the sponsor were to offer a price reduction, it would be prepared to consider the matter again out-of-session.</p> <p>The PBAC indicated that any restriction on the listing of docetaxel should stipulate use as first-line chemotherapy, a minimum Karnofsky score of 60%, that dosing must be on a 3-weekly basis (there was no survival difference when weekly dosing was used) and a maximum of 10 cycles.</p> <p><i>(See also positive recommendations from July 2007)</i></p> |
|  |                        | <p>Sponsor's comments</p>  | <p>The sponsor is considering the PBAC proposal</p>   |