| **SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE AND USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** | |
| --- | --- | --- | --- | --- |
| ELECTROLYTE REPLACEMENT, ORAL,  Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10,  O.R.S.®  Alphapharm Pty Ltd  Other Business  (Change to listing) | Rehydration in intestinal failure | To seek the Pharmaceutical Benefits Advisory Committee's (PBAC) advice on whether it would be appropriate to amend the listing of O.R.S.® on the Pharmaceutical Benefits Scheme (PBS) to include the indication ‘Rehydration in intestinal failure’ under the same circumstances as the previous brand listed for this indication. | Recommended | The PBAC recommended amending the current PBS listing of O.R.S.® to include the indication ‘Rehydration in intestinal failure’ under the same circumstances and equivalent approved ex-manufacturer price as the previous listing of this drug for this indication. |
| LENALIDOMIDE  All forms  Revlimid®  Celgene Pty Limited  POMALIDOMIDE  All forms  Pomalyst®  Pomolide®  Pomalidomide Sandoz**®**  Celgene Pty Limited  Juno Pharmaceuticals Pty Ltd  Sandoz Pty Ltd  Other Business  (Change to listing) | Multiple Myeloma | To seek the PBAC’s advice on the appropriateness of brand substitution at the pharmacy level (‘a’‑flagging) between brands of each drug and how the restriction text should make reference to the sponsor specific, patient risk management programs. | Recommended | The PBAC advised that the bioequivalent brands of lenalidomide and pomalidomide respectively should not be considered equivalent for the purposes of substitution (i.e., ‘a’-flagged in the Schedule).  While the PBAC was supportive in principle of ‘a’-flagging between brands of bioequivalent medicines, it advised this was not practical for pomalidomide and lenalidomide while sponsor/brand specific patient risk management programs exist for these drugs. The PBAC noted potential for unnecessary administrative burden and confusion for prescribers and pharmacists that may delay patient access where an alternative brand is sought.  The PBAC also provided advice as to how the restriction text could be modified to reflect the different patient risk management programs. |