

## **Special Pricing Arrangement (SPA) criteria**

1. The medicine treats a significant medical condition, and the Pharmaceutical Benefits Advisory Committee (PBAC) advises that it generates substantial incremental benefit for the intended patient population;
2. The PBAC advises that the medicine has unique characteristics compared to any available alternative therapies or the medicine is recommended for listing in comparison with a medicine which has a similar arrangement;
3. The effective price is consistent with or less than the price at which the medicine is recommended by the PBAC as being acceptably cost-effective, and there is significant financial benefit that would accrue to the Commonwealth should the arrangement be agreed, compared to subsidising at the published price;
4. To the extent that the medicine is subsidised in other countries which have similar public subsidy arrangements for medicines and the Responsible Person (Sponsor) has advised the Department of Health, the effective price and any proposed arrangements, are consistent with those applying for the medicine in these countries;
5. The Sponsor advises that not entering into a 'published' versus 'effective' pricing arrangement would prevent listing, and provides:
  - a) the reason/s, including financial implications, why this arrangement is required;
  - b) confirmation that all other options for listing have been explored, and that acceptance of this type of arrangement is as a last resort;
  - c) acknowledgement that acceptance of an agreement to any arrangement, is at the discretion of the Commonwealth;
  - d) acceptance that the existence of a Deed of Agreement which contains a 'Special Pricing Arrangement' will be published in the Schedule of Pharmaceutical Benefits, as well as the Therapeutic Relativity Sheets; and
  - e) acceptance that to give effect to any pricing arrangement a Deed of Agreement is required between the Sponsor and the Commonwealth.