

3.04 STRONTIUM

Sachet containing granules for oral suspension containing strontium ranelate 2 g; Protos 2 g®; Servier Laboratories (Aust.) Pty Ltd.

1 Purpose of item

- 1.1 The Minister (through the Delegate) requests the Pharmaceutical Benefits Advisory Committee (PBAC) provide advice under Section 101(4AAB) of the *National Health Act 1953* (the Act) in relation to the proposed revocation of the declaration that strontium is a drug to which Part VII of the Act applies.
- 1.2 The Minister is seeking this advice prior to making a decision on whether to delist strontium from the Schedule of Pharmaceutical Benefits (PBS).

2 Background

- 2.1 In accordance with Section 101 (4AAA), the Minister may, by legislative instrument, revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation.

Pursuant to Section 101 (4AAB):

- If:
- (a) under subsection (4AAA), the Minister proposes to revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation; and
 - (b) on and after the day the revocation or variation comes into force, the drug or medicinal preparation would cease to be a listed drug;

then, before making the revocation or variation, the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation.

- 2.2 There have been 13 previous PBAC considerations of strontium ranelate. At the July 2014 meeting, the PBAC indicated that it was inclined to recommend the delisting of strontium ranelate from the PBS. However, the PBAC also considered that it would be appropriate for the sponsor to first have the opportunity to establish the cost-effectiveness of strontium ranelate in a restricted PBS population (patients with severe established osteoporosis unable to use other treatments due to contraindication or intolerance).
- 2.3 At its most recent PBAC consideration in July 2015, the PBAC recommended that strontium ranelate remain listed on the PBS for the treatment of severe established osteoporosis in patients unable to use other osteoporosis medications and without cardiovascular contraindications.
- 2.4 The PBAC further considered that a pragmatic approach would be to recommend continued listing of strontium ranelate on the condition that the price is reduced such that the ICER would be less than \$15,000- \$45,000/QALY. The PBAC considered that an ICER of less than \$15,000- \$45,000/QALY would be broadly in line with

previous PBAC considerations of drugs for this indication and in line with the ICER that the submission had initially proposed.

- 2.5 A further reduction in the offered dispensed price for maximum quantity (DPMQ) price of \$ [REDACTED] is required to achieve this ICER.
- 2.6 The following table outlines the results of the economic analysis from the July 2015 PBAC submission.

Table 1: Results of economic analysis from July 2015 submission.

Analysis	ICER
Submission base case.	\$ [REDACTED]
Commentary correction of errors, exclusion of non-significant effects and fracture recovery period of 3 years.	\$ [REDACTED]
Pre-Sub-Committee Response [REDACTED] % price reduction of DPMQ to \$ [REDACTED].	\$ [REDACTED]
Pre-PBAC response [REDACTED] % price reduction of DPMQ to \$ [REDACTED].	\$ [REDACTED]

DPMQ= dispensed price for maximum quantity

3 Current situation

- 3.1 During post-PBAC pricing negotiations between the Department and the sponsor, Servier advised that the pre-PBAC response offer of DPMQ \$ [REDACTED] per pack of 28 sachets remains their best proposal.
- 3.2 As this price results in an ICER that is not consistent with the PBAC recommendation, on 17 September 2015, the Department notified the sponsor of the Minister’s (through the Delegate) intention to consider revoking the declaration that strontium is a drug to which Part VII of the Act applies. The sponsor was also requested to provide any additional information for PBAC consideration alongside the Minister’s request for advice under Section 101(4AAB) of the Act.
- 3.3 Servier’s response of 8 October 2015, noted that the July 2015 PBAC minutes regarding strontium indicate that, in a small and declining patient population, strontium is the only treatment option for severe osteoporosis. The response further reiterated the figures presented to the July 2015 PBAC (DPMQ \$ [REDACTED] per pack of 28 sachets maintaining an ICER of \$45,000/QALY – \$75,000/QALY) for the continued listing of strontium ranelate on the PBS.
- 3.4 Medicare statistics for strontium have been compiled in the following tables and figures.

Table 2 and Figure 1: Medicare statistics - strontium ranelate services.

3036T (services)	Year 2013	Year 2014	2015 Jan-Jun
General	40,605	34,137	8,806
Concession	228,160	188,368	49,676
RPBS	16,741	12,539	2,938
Total services	285,506	235,044	61,420

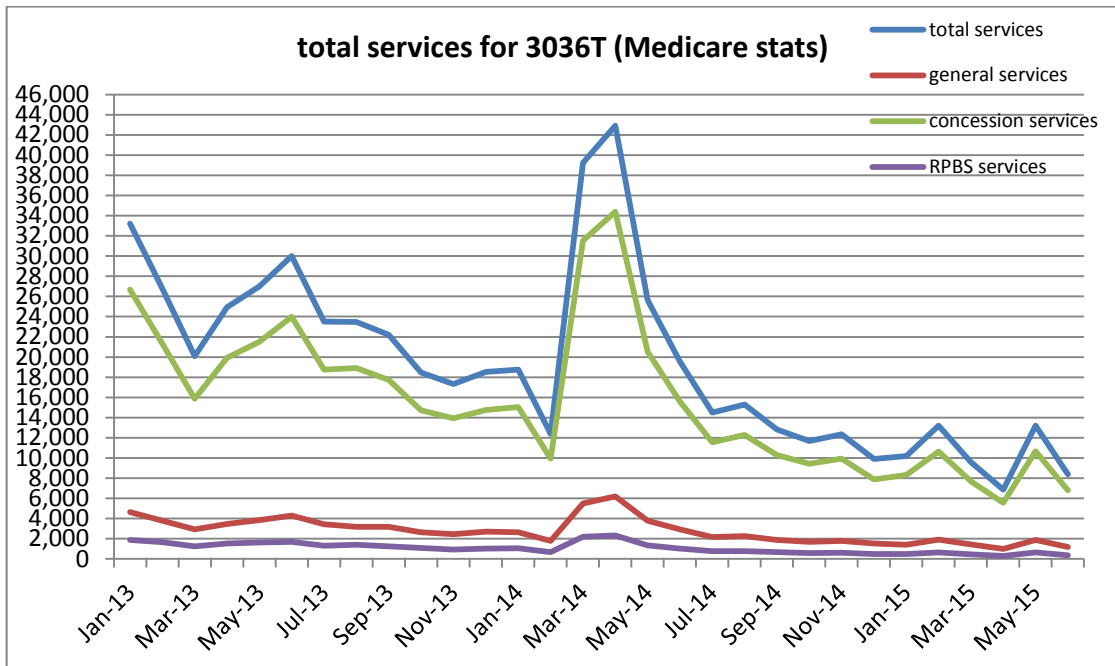
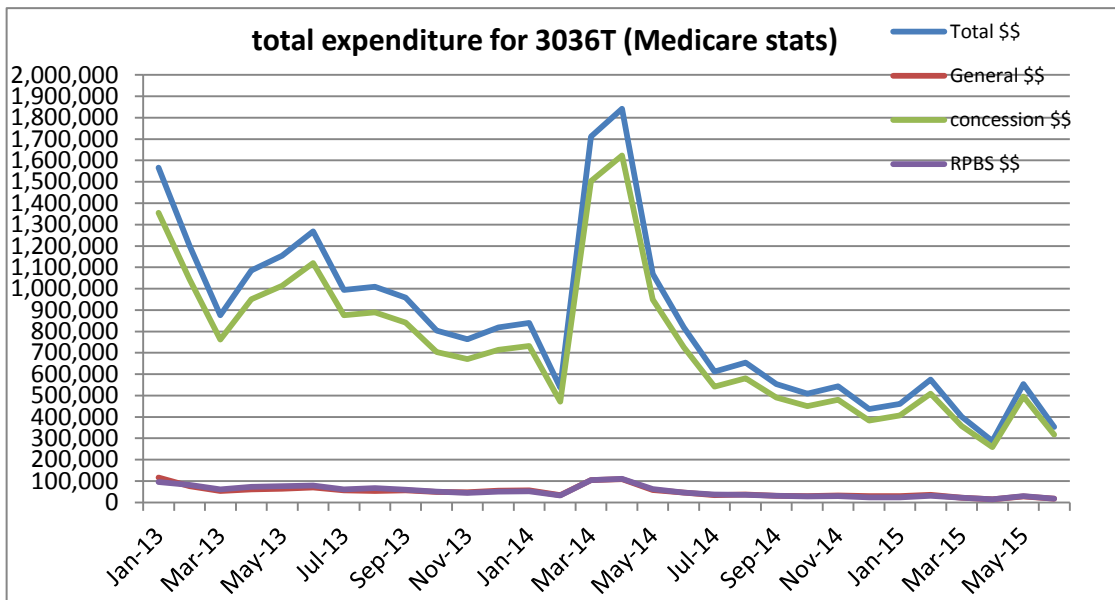


Table 3 and Figure 2: Medicare statistics - strontium ranelate expenditure.

3036T (expenditure)	Year 2013	Year 2014	2015 Jan-Jun
General	\$ 759,581	\$ 600,944	\$ 145,692
Concession	\$ 10,940,518	\$ 8,932,558	\$ 2,344,674
RPBS	\$ 799,386	\$ 592,265	\$ 138,342
Total expenditure	\$ 12,499,485	\$ 10,125,767	\$ 2,628,708



4 PBAC Outcome

- 4.1 The PBAC considered the sponsor's submission of 9 September 2015.
- 4.2 The PBAC noted that the sponsor's submission offered a cumulative ■■■% price reduction consistent with the July 2015 Pre-PBAC Response, in addition to the 5% reduction occurring 1 April 2016. The Committee noted that after accounting for both reductions the ICER remained significantly higher than the original ICER of \$15,000/QALY - \$45,000/QALY which formed the basis for the PBAC's listing recommendation in July 2015.
- 4.3 The PBAC further noted that the Pre-PBAC Response of 8 October 2015 did not provide any new evidence where an ICER of greater than \$15,000/QALY - \$45,000/QALY could be supported.
- 4.4 The PBAC reaffirmed its previous advice of July 2015 that the continued listing of strontium on the PBS, for the treatment of severe established osteoporosis in patients unable to use other osteoporosis medications and without cardiovascular contraindications, be based on the condition that the price is reduced such that the ICER would be less than \$15,000/QALY - \$45,000/QALY.
- 4.5 The PBAC reaffirmed that at its current price, strontium is not cost-effective.
- 4.6 The PBAC recognised that the Minister may choose to delist strontium from the PBS unless an appropriate price offer is received from the sponsor.
- 4.7 The PBAC considered that there were no reasons why the Minister should not delist strontium by revoking the declaration that strontium is a drug to which Part VII of the Act applies, if the sponsor of strontium does not agree to the price reduction sought following the July 1015 meeting of the PBAC.
- 4.8 The PBAC noted that, if delisting of strontium is to proceed, then for the few patients requiring treatment with this medicine, it remains accessible via the private and public hospital settings.
- 4.9 There were no other matters that the PBAC considered the Minister should take into account when considering whether or not to delist strontium from the PBS.

5 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

6 Sponsor's Comment

The sponsor had no comment.