



**THE HON SUSSAN LEY MP
MINISTER FOR HEALTH
MINISTER FOR SPORT**



Ref no: MC15-014856

Dr Dennis Jensen MP
Chair
Standing Committee on Petitions
Parliament House
CANBERRA ACT 2600

Dear Dr Jensen

Dennis

Thank you for your letter of 18 August 2015 regarding a petition presented to you on 17 August 2015, requesting the relisting of Sensipar[®] (cinacalcet) on the Pharmaceutical Benefits Scheme (PBS).

Sensipar, a medicine used for the treatment of chronic kidney disease, was removed from the PBS on 1 August 2015, at the request of its sponsor, Amgen Australia Pty Ltd. The Australian Government cannot compel a company to continue to make a medicine available through the PBS, if the company concerned does not wish to do so.

Sensipar was listed on the PBS on 1 July 2008 for the treatment of certain patients with chronic kidney disease who are undergoing dialysis. The listing, based on the recommendations of the independent Pharmaceutical Benefits Advisory Committee (PBAC), was subject to a risk-sharing arrangement with the sponsor.

The agreement required Amgen Australia to prove that the survival benefit claimed at the time of the initial PBS listing was confirmed by ongoing data derived from the largest kidney disease mortality trial ever conducted, the EVOLVE trial.

This risk-share agreement pre-dated the formal introduction of Managed Entry Schemes under the PBS in 2011 and provided a precedent for listings where the sponsor is required to provide further data after a defined period of time to support the claim of cost-effectiveness and the initial agreed price for the medicine.

Details of the basis upon which Sensipar was recommended for listing are publicly available via the Public Summary Document, which can be found on the PBS website at: www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2007-11/pbac-psd-cinacalcet-hydrochloride-nov07.

Based on new evidence from the EVOLVE trial, the PBAC drew the conclusion that Sensipar no longer demonstrated cost-effectiveness, a necessary criterion for PBS listing. For example, the primary outcome of the trial found that in relation to survival, Sensipar was no better than placebo.

In general, the PBAC tries to ensure that patients in the community have reasonable access to medicines required for the treatment of serious medical conditions. However, the PBAC also has a responsibility to the community as a whole to ensure that, as far as possible, medications listed as benefits are used in medically effective ways which provide good value-for-money to taxpayers.

My Department has worked with the sponsor of Sensipar and NPS MedicineWise to ensure that medical practitioners and consumers have the information they need to manage the transition to another medicine.

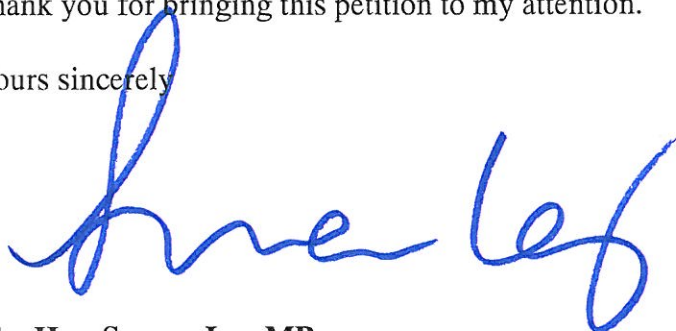
Alternative PBS listed therapies for chronic kidney disease include phosphate binders, such as sevelamer (Renagel[®]) and calcium carbonate (Cal-sup[®]).

I understand that Amgen Australia has undertaken to supply Sensipar free-of-charge to a selected group of at risk patients via a special access programme. Affected patients are best advised to consult their kidney specialists for advice about whether they are likely to qualify for access to this programme and on the most appropriate alternative treatment options.

I note that Amgen Australia has advised in its 'Important Information for Patients Currently Treated with Sensipar' information sheet that 'Sensipar can be safely stopped after discussion with your nephrologist.'

Thank you for bringing this petition to my attention.

Yours sincerely



The Hon Sussan Ley MP

28 AUG 2015