The Hon Greg Hunt MP
Minister for Health and Aged Care

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10 SEP 2021

Mr Ken O'Dowd MP
Chair
Standing Committee on Petitions
Parliament House
CANBERRA ACT 2600
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Dear Chair

I refer to your correspondence of 9 August 2021 on behalf of petitioners concerned about the removal of the Avastin® brand of the medicine bevacizumab, from the Pharmaceutical Benefits Scheme (PBS) from 1 June 2021 (petition number EN2697).

The medicine bevacizumab has been eligible for subsidy through the PBS prior to and after 1 June 2021 and has not been subject to any reported medicine shortages. Bevacizumab is a biological medicine used to treat a range of cancers, including metastatic colorectal cancer, a form of bowel cancer. Bevacizumab is available in two vial strengths, 100 mg in 4 mL injection and 400 mg in 16 mL injection.

The Avastin brand of bevacizumab was removed from the PBS at the request of the manufacturer, Roche Products Pty Ltd (Roche), following a decision to discontinue Avastin in Australia.

Notices of Roche's decision to discontinue Avastin in Australia have been published on the Therapeutic Goods Administration (TGA) website at: apps.tga.gov.au/Prod/msi/Search/Details/bevacizumab. The 100 mg in 4 mL injection was discontinued from the market on 30 June 2021 and the 400 mg in 16 mL injection will be discontinued from the market on 3 December 2021. Roche has advised the reason for the discontinuation is due to 'commercial changes/commercial viability'.

Medicine manufacturers are private entities that make their own decisions regarding their products, and cannot be compelled by the Government to continue to list a product on the PBS or to continue to market their product in Australia. When a medicine manufacturer discontinues their product, the subsequent decision to keep or remove the product from the Australian Register of Therapeutic Goods lies with the medicine manufacturer.

The biosimilar brand of bevacizumab, Mvasi®, has been listed on the PBS from 1 June 2021. Mvasi has been assessed by the TGA, Australia's medicine and therapeutic regulatory agency, to be highly similar to the Avastin brand, based on evidence from comparability and clinical studies. This means patients can be assured that Mvasi provides the same health outcomes, and is as safe and effective, as Avastin.

Regulatory standards for biosimilar medicines have been carefully developed over 20 years, through a collaborative effort among major regulatory agencies worldwide, including agencies in the United States, Europe, Canada, and Australia. Mvasi obtained regulatory approval in the United States in 2017 and Europe and Canada in 2018, and currently has regulatory approval in many other countries.

All manufacturing sites used for medicines supplied in Australia, whether located in Australia or overseas, must be approved by the TGA. All manufacturing facilities must comply with Australian manufacturing standards and are regularly inspected and monitored to help ensure compliance. This means that all medicines supplied in Australia are manufactured to the same standards whether they are manufactured in Australia or in an overseas country. Biosimilar medicines are manufactured in facilities that met the same standards as the innovator medicine.

Under legislation the Australian Government cannot list a product on the PBS unless the Pharmaceutical Benefits Advisory Committee (PBAC) – an independent, expert advisory committee - makes a recommendation in favour of its listing.

The PBAC considered applications for Mvasi to be listed on the PBS in November 2020 and March 2021. The PBAC recommended Mvasi and Avastin should be treated as equivalent. The PBAC provided this advice after considering clinical evidence provided by the manufacturer of Mvasi and advice from the TGA.

The PBAC also recommended that bevacizumab be PBS listed as an unrestricted benefit, which allows subsidised access to bevacizumab for all Australians who receive a script for this medicine from their prescriber. This change was implemented from 1 June 2021.

The Government worked with the manufacturer of Mvasi to ensure continuity of supply of bevacizumab on the PBS from 1 June 2021.

The following resources are available to support both patients and healthcare professionals through this change:

- Information on changes to the PBS listings published in RADAR, a journal for healthcare professionals published by NPS MedicineWise at: www.nps.org.au/radar/articles/bevacizumab-biosimilar-now-pbs-listed. NPS MedicineWise is an independent organisation funded by the Government to provide services supporting quality use of medicines.
- A fact sheet explaining the PBS listing changes for bevacizumab from 1 June 2021 that is available on the Biosimilar Awareness Initiative webpage of my Department's website at: www.health.gov.au/internet/main/publishing.nsf/Content/biosimilar-awareness-initiative.
- The Australian Public Assessment Report (AusPAR) for Mvasi of November 2020, which is available on the TGA website at: www.tga.gov.au/auspar/auspar-bevacizumab-4.
- The Public Summary Document for Mvasi from the November 2020 and March 2021 meetings of the PBAC, documenting the Committee's recommendations on subsidising Mvasi on the PBS, available at: www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd by searching for the relevant meeting dates.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt