Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1172.1 – BRAF mutation test for treatment of metastatic melanoma for access to vemurafenib

Applicant: **Roche Products Pty. Ltd.**

Date of MSAC consideration: **MSAC 66th Meeting, 30-31 March 2016**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

The application sought an amendment to Medicare Benefits Schedule (MBS) item 73336 based on the previous April 2013 recommendation by MSAC (Application 1172) to defer MBS listing of *BRAF* testing pending a Pharmaceutical Benefits Advisory Committee (PBAC) recommendation to list vemurafenib on the Pharmaceutical Benefits Scheme (PBS). The Department received the evidence for the resubmission on 3 November 2015.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the comparative safety, clinical effectiveness and cost-effectiveness MSAC supported public funding for *BRAF* genetic testing in patients with unresectable (Stage III) or metastatic (Stage IV) melanoma for access to vemurafenib.

MSAC supported the addition of vemurafenib to MBS Item 73336.

3. Summary of consideration and rationale for MSAC's advice

MSAC recalled that BRAF testing in the context of a co-dependent application to determine eligibility for proposed PBS-subsidised vemurafenib (a BRAF inhibitor) in patients with unresectable Stage III or Stage IV metastatic cutaneous melanoma had been deferred at its August 2012 and April 2013 MSAC meetings. After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of *BRAF* V600 mutation testing, MSAC had deferred the applications until PBAC reconsidered the PBS listing of vemurafenib.

MSAC noted that in this resubmission the applicant was seeking an amendment to MBS item 73336 to include reference to vemurafenib. The existing MBS item is for *BRAF* V600 mutation testing for access to dabrafenib (a BRAF inhibitor).

MSAC noted that vemurafenib in combination with cobimetinib (a MEK inhibitor) was recommended for listing in the PBS at the March 2016 PBAC meeting for *BRAF* V600 positive, unresectable Stage III or Stage IV melanoma. The resubmission was based on the coBRIM phase III trial in which vemurafenib was used in combination with cobimetinib. The resubmission claimed this combination is non-inferior in efficacy and safety to that of the currently used dabrafenib.

MSAC recalled that it had been supportive of a *BRAF* V600 mutation testing MBS item including reference to both vemurafenib and dabrafenib at its April 2013 meeting. MSAC accepted the applicant's argument that the addition of vemurafenib to MBS item 73336 would be cost neutral, as vemurafenib will substitute dabrafenib, resulting in no growth in the number of patients treated. In addition, MSAC noted that a diagnostic test for cobimetinib was not required to identify patients suitable for treatment.

4. Background

The original submission details can be found in the Public Summary Document for Application 1172, http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1172-public

5. Applicant's comments on MSAC's Public Summary Document

The applicant had no comments.

6. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.