

<b>Title:</b>	<b>M-VAX™ – a treatment for patients with advanced stage III melanoma</b>
<b>Agency:</b>	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia
<b>Reference:</b>	MSAC Application 1049 Assessment Report First printed: January 2003 <a href="http://www.msac.gov.au">http://www.msac.gov.au</a> ISBN 0 642 82 187 9

### **Aim**

To assess the safety, effectiveness and cost-effectiveness of M-VAX™, a treatment for patients with advanced stage III melanoma, relative to observation.

### **Conclusions and results**

#### **Safety**

Mild nausea and vomiting occur in the majority of patients receiving M-VAX™, probably secondary to the use of cyclophosphamide. Injection site reactions are also common. Other adverse reactions are poorly reported. In the US, there have been several reports of contaminated vaccine being administered to patients. After reviewing the available evidence, it was concluded that it is not possible to perform a reliable assessment of the relative safety of M-VAX™ and observation. This is because only uncontrolled and poorly reported data are currently available for M-VAX™.

#### **Effectiveness**

At present, the highest level of evidence available to describe the efficacy of M-VAX™ as an adjuvant treatment for stage IIIB and IIIC melanoma, is level IV evidence. The primary evidence is data collected in four prospective, phase II, uncontrolled clinical trials. The dose regimens vary across the four trials, with none being consistent with the dose regimen for which reimbursement is being sought. On the basis of the available data, it is not possible to assess the relative efficacy of M-VAX™ and observation without the introduction of considerable bias.

#### **Cost-effectiveness**

There are insufficient data available to make a valid assessment of the relative efficacy of M-VAX™ and observation. Therefore, it is not possible to estimate the cost-effectiveness of M-VAX™ relative to observation. However, M-VAX™ is considerably more costly than observation (~\$39,000 per patient).

#### **Recommendation**

MSAC recommended that on the strength of evidence pertaining to M-VAX™, a treatment for patients with advanced stage III melanoma, public funding should not be supported for this procedure. The Minister for Health and Ageing accepted this recommendation on 8 October 2002.

#### **Methods**

MSAC conducted a systematic review of the medical literature pertaining to M-VAX™ and observation. A thorough search of the medical literature was carried out via electronic databases and health technology assessment websites. Those citations that met predefined inclusion criteria were included in the review of evidence.