Internal Memo
Ministry Of Health

To: Anthony Hill, Deputy Director-General, Regulation and Governance Directorate

From: Sarah Reader, Manager Product Regulation, Medsafe

Subject: **Referral of New Medicine Applications to the Medicines Assessment Advisory Committee**

Date: 1 December 2009

For Your: ACTION: (√) DECISION: ( ) INFORMATION: ( )

Section 20 of the Medicines Act 1981 requires that no person shall sell, distribute or advertise any new medicine before the consent of the Minister of Health has been notified in the *New Zealand Gazette*. You are the Minister's delegate for the purpose of granting consent to distribute a new medicine.

Section 22 of the Medicines Act 1981 requires that if, after considering an application, the Minister is not satisfied that consent to distribute the new medicine should be granted, he must seek a recommendation from the appropriate committee on the decision he should make. The Medicines Assessment Advisory Committee (MAAC) is the committee established under section 8 of the Medicines Act 1981 to provide advice in relation to the approval of medicines.

Having completed the evaluation of an application for consent to distribute Sativex oral spray Medsafe is unable to recommend that you grant consent for the reasons set out in the attached letter to the applicant.

You are therefore recommended to refer this application to the MAAC for consideration and to sign the attached letter advising the applicant of your action. You will be advised of the committee's recommendation in due course.

Recommendations:

1.	**Refer** the application for consent to distribute the new medicine Sativex oral spray to the Medicines Assessment Advisory Committee for consideration.	**Yes / No**
2.	**Sign** the attached letter advising the applicant of your action and the reasons for it.	**Yes / No**

Sarah Reader
Manager Product Regulation
Medsafe

Anthony Hill
Deputy Director-General
Regulation and Governance
Directorate

Date: 7-12