

AGREEMENT TO TREATMENT DIRECTIONS

AUTHORISATION OF PRESCRIBERS UNDER SECTION 19(5) OF THE
THERAPEUTIC GOODS ACT 1989

Unregistered drug to be supplied (prescribed): TAFENODIVINE

Route of administration / dosage form: ORAL (Capsule)

Condition / reason for prescribing: Recurrent P. vivax

Supplier's name and address: SK-B v.a AMI Rathipadi Bangalore MNS 4012

Name of Body endorsing this application: AMI as above

I understand that:

the product is not registered for marketing in Australia and that the Therapeutic Goods Administration (TGA) is unable to vouch for the quality, safety or efficacy of this unregistered product, and that its use is regarded as experimental.

the giving of an authority under subsection 19(5) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of, therapeutic goods by that person or another person.

the product may be prescribed only for patients in an authorised prescriber immediate care.

an authorised prescriber must continue to have an appropriate endorsement in order to supply the drug.

That is, an authorised prescriber must be a medical practitioner engaged in clinical practice at a hospital and having the endorsement of the ethics committee of that hospital for the purpose of supply of that drug, or a medical practitioner endorsed by a relevant specialist medical college or specialist medical society for the purpose of supply of the drug.

the Secretary of the Department of Health and Aged Care may give notice of revocation of this authorisation at any time and that any authorisation would be valid only until revoked or until the specified product or a similar product is registered in Australia, whichever is the earlier.

I agree to:

obtain from each patient (or guardian) consent in relation to the proposed use of the unregistered product, and in this context, inform the patient that the product is not registered in Australia.

report any suspected adverse reactions to the TGA.

to provide the TGA with a quarterly report on the number of patients for whom I have prescribed the product.

to comply with all relevant State/Territory legislation.

Signature: George Blackwood Date: 11 APR 00

Medical Practitioner's name and address: Dr George Blackwood
Balmford Naval Base
Middle Head Rd.
MOSMAN 2088

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