MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

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4 April, 2016

TT50-9958
(1947)
16/SCOTT/22)

Ms Michelle Baker
Quintiles Pty Ltd (NZ)
Level 4, Symonds Centre
49-51 Symonds Street
AUCKLAND 1010

Dear Ms Baker

CBT 124 (bevacizumab) and Avastin (bevacizumab)
Protocol Number: CBT124/NHV/001

This letter acknowledges receipt of your clinical trial application under the provisions of Section 30 of the Medicines Act 1981 received by Medsafe on 1 April 2016. Your application as submitted meets the eligibility criteria for the abbreviated approval process and I am pleased to advise you that this clinical trial has been approved by the Director-General of Health.

You are therefore authorised to distribute CBT 124 (bevacizumab) and Avastin (bevacizumab) for the purposes of this clinical trial to the following approved investigator(s):

Approved Investigators	
Name	Site
Dr Christian Schwabe	Auckland Clinical Studies Limited 3 Ferncroft Street Grafton AUCKLAND

The applicable fee for this notification, based on the information provided on your form, is detailed on the attached invoice. Payment of the invoice is requested within 7 days. Please ensure you quote the invoice number when payment is made.

Please note that it is your responsibility to obtain HDEC approval before your trial can commence in New Zealand.

Legal reporting and record keeping requirement

It is a requirement of the Medicines Act 1981 that you

1. report the progress of the trial to the Director-General of Health at six monthly intervals;
2. report the results of the trial to the Director-General of Health on completion of the trial;
3. report serious adverse reactions which occur during the trial to the Director-General in accordance with the requirements of the Guideline on the Regulation of Therapeutic Products in New Zealand, Part 11: Clinical trials – regulatory approval and good clinical practice requirements;
4. keep complete and accurate records of all quantities of the trial medicine supplied during the trial;
5. ensure that every label on every package or container of the trial medicine bears the words "To be used by qualified investigators only" or words of similar meaning.

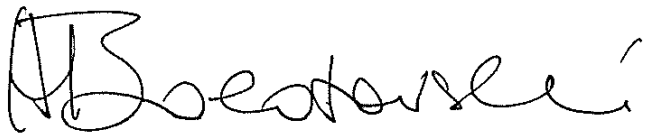
Additional reporting requirements
If a patient of a medical practitioner who is not an investigator is a trial subject, that medical practitioner should be kept informed of the progress of the trial.

Importation of the trial medicine
If requested, you should present this letter to New Zealand Customs as evidence that the Ministry of Health has no objection to the importation of this clinical trial medicine.

Importation of any investigational product which contains controlled drugs that are scheduled under the Misuse of Drugs Act also require additional Licence(s). It is your responsibility to ensure that you have the appropriate licences before you commence importation of any investigational product which contains controlled drugs. For further information regarding this process and an application form please contact Medicines Control at medicinescontrol@moh.govt.nz

In all further correspondence concerning this medicine, please quote the file reference TT50-9958 (1947).

Yours sincerely



Dr Alexander Bolotovski
for Director-General of Health