COPY

MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

3 August 2004

TT50-7090

Dr Jane O'Hallahan
Director,
Meningococcal Vaccine Strategy
Public Health Group
Ministry of Health
PO Box 5013
Wellington

Dear Jane,

Meningococcal B vaccine issues.

I have now completed a review of all of the reports associated with the approval process for the meningococcal B vaccine (MeNZB).

With regard to the quality data relating to the vaccine, the approval under the requirements of Section 23 of the Medicines Act 1981, was granted on the basis that Chiron would provide further quality data. This has been confirmed to Chiron and some of the additional data have already been supplied.

The Vaccine Sub-committee (VSC) met on 5 April 2004 to discuss the clinical issues associated with the vaccine. The minutes of that meeting note that the VSC agreed that a letter be sent to the Director of the Meningococcal Vaccine Strategy team advising that as a condition of provisional consent of this product the following would be required to be carried out by the Meningococcal Vaccine Strategy Team and reported back to Medsafe:

- Informed consent forms be provided to person about to be vaccinated (or parent/guardian in the case of children under the age of 15years). These forms clearly identify concerns about efficacy.
- Laboratory diagnosis of Meningococcal infection
- Identification of vaccine failure.

I am now confirming this condition of the VSC which was raised during the consideration of the data. For additional information, I have attached a copy of the full minutes of the VSC meeting to this letter for your information.

Level One ASB Bank
8-12 Link Drive
Wairau Park
PO Box 100 166
North Shore Mail Centre
Auckland

Level 18
Grand Plimmer Tower
2-6 Gilmer Terrace
PO Box 5013
Wellington
Phone (04) 496 2000

3rd Floor
John Wickliffe House
Princes Street
PO Box 384
Dunedin
Phone (03) 479 2561

As the requirement noted by the VSC is quite specific, I seek your confirmation that these conditions are being met on an ongoing basis.

Yours sincerely,

Rob Allman

Rob Allman
Team Leader, Evaluation Team.