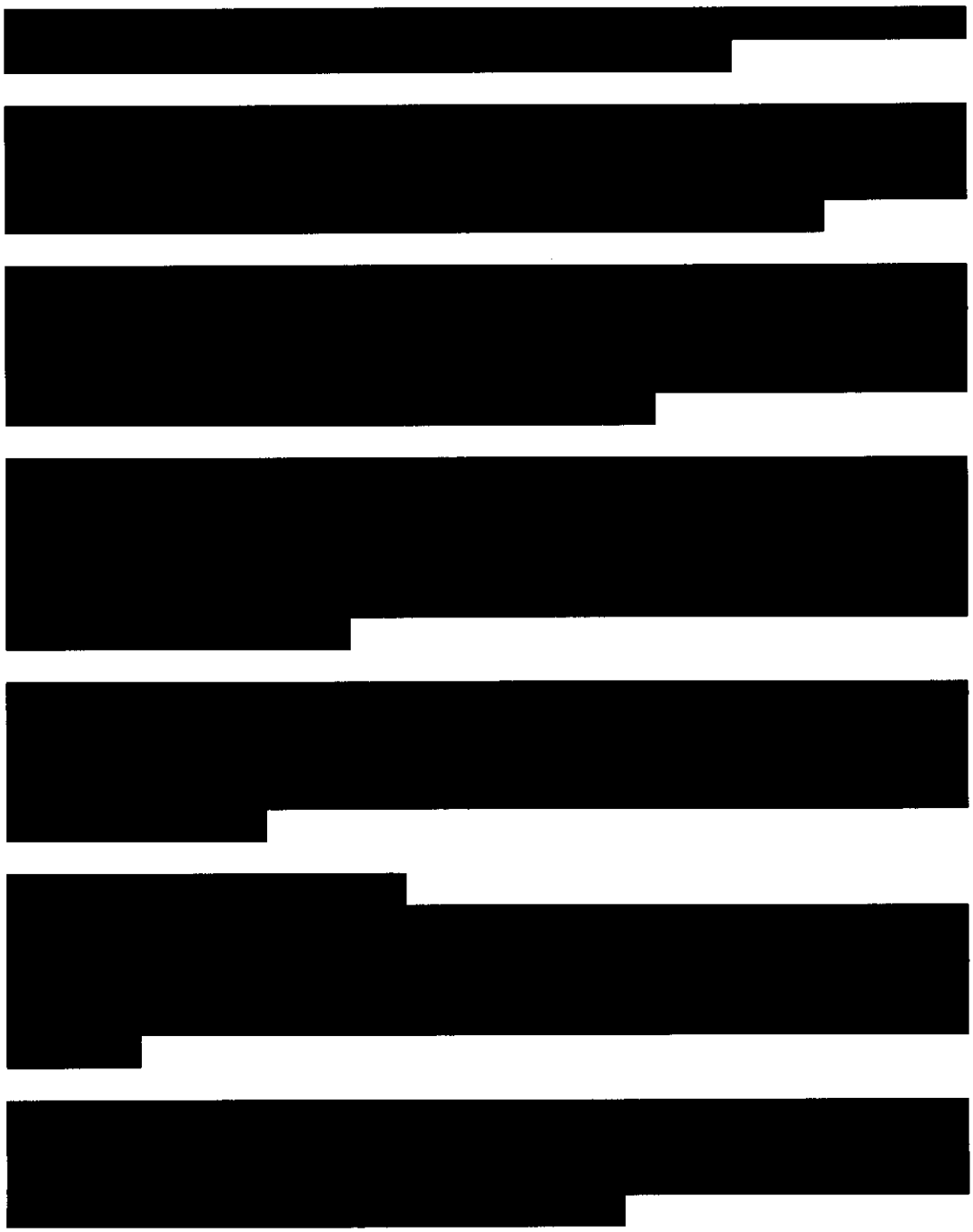

7. ITEMS FOR RATIFICATION

7.1 VACCINE SUBCOMMITTEE BUSINESS

7.1.1 MeNZB (meningococcal B) vaccine. TT50-7090

The Vaccine Subcommittee met on the 25 June 2007, to consider an application for full consent for MeNZB (meningococcal B) injection suspension. The application was gazetted under section 23 of the Medicines Act 1981 on 8 July 2004 and provisional consent was renewed on 8 July 2006.

The Vaccine Subcommittee discussed additional data submitted by Novartis Vaccines and Diagnostics in January 2007 in the form of:

1. A report on the Poisson Regression Modelling of the Effectiveness of the Meningococcal B Vaccine (MeNZB) prepared by the School of Mathematics, Statistics & Computer Science, University of Victoria, Wellington.

2. An update of the adverse reactions report prepared by the Centre for Adverse Reactions Monitoring (CARM) and the Meningococcal Vaccine Strategy Data Management Group in August 2006.

The Vaccine Subcommittee noted that the data were to a large extent a further analysis of the data which they had previously seen.

The Vaccine Subcommittee concluded that the Poisson Regression Model measured the effectiveness of the vaccine over the short term, however there were insufficient data presented in the study report to demonstrate long-term effectiveness.

The Vaccine Subcommittee reaffirmed its earlier decision that measurement of Serum Bactericidal Antigen results (SBA) remained the only appropriate marker for the assessment of immunogenicity and efficacy of the vaccine, and the studies that demonstrated waning SBA levels were strong indicators that the immune response to vaccination with MeNZB would not be sustained in the majority of vaccinated children. The committee concluded that the evidence provided supported the effectiveness of the vaccine as a suitable intervention to manage, or break, an epidemic, but the vaccine could not be approved as a means to provide long term protection. In order for the vaccine to e given full consent, the company would need to provide longer term evidence of efficacy and prolonged immunogenicity.

Committee recommendations:

The current provisional consent under Section 23 of the Medicines Act 1981 is still appropriate until acceptable long-term efficacy data are available.

[redacted]