

## IMAC Statement, 2 June 2005

Re: The May 2005 Meningococcal Gold Rush, second edition, press release by Barbara Sumner-Burstyn and Ron Law.

This 61-page edition introduces no new meaningful data to the information on MeNZB™ that has not already been considered and responded to.

From the scientific angle there is a clear evidence base supporting the MeNZB™ immunisation programme to control the current epidemic and a wide-ranging safety-monitoring programme in place.

**Parents and members of the public** who wish to explore the issues raised can access evidenced based information from the following sources:

- General issues related to MeNZB™ vaccine phone to discuss 0800 20 30 90 or visit [www.immunise.moh.govt.nz](http://www.immunise.moh.govt.nz)
- General issues on immunisation in New Zealand phone to discuss 0800 IMMUNE 466 863 or visit [www.immune.org.nz](http://www.immune.org.nz)
- Response to first press release Meningococcal Gold Rush by Barbara Sumner-Burstyn and Ron Law (Dec 2004). Available from [www.immune.org.nz](http://www.immune.org.nz)

For those conducting **further independent research** evidence based information can be found at:

### **Peer Reviewed Publications - Recommended Readings**

#### **Meningococcal Disease – description, diagnosis, treatment and cause**

- Rosenstein NE, Perkins BA, Stephens DS, Popovic T, Hughes JM. Meningococcal Disease. New England 2001;344(18):6.
- Thomas M. Prevention of group B meningococcal disease by vaccination: a difficult task. The New Zealand Medical Journal 2004;117(1200):<http://www.nzma.org.nz/journal/117-1200/1016/>.

#### **Incidence of Meningococcal Disease in New Zealand – Epidemiology**

- Lopez L, Martin D. Meningococcal Disease report January to December 2004. Wellington: Ministry of Health; 2005.

#### **What puts us more at risk for meningococcal disease?**

- Baker M, McNicholas A, Garrett N, Jones N, Stewart J, Koberstein V, et al. Household crowding a major risk factor for epidemic meningococcal disease in Auckland children. Pediatric Infectious Disease Journal 2000;19(10):983-90.

### **Natural Protection against meningococcal disease**

- Pollard AJ, Frasch C. Development of natural immunity to *Neisseria meningitidis*. *Vaccine* 2001;19:1327-46.
- Goldschneider I, Gotschlich EC, Artenstein MS. Human immunity to the meningococcus. I. The role of humoral antibodies. *J Exp Med* 1969;129(6):1307-26, 1969 Jun 1.
- Goldschneider I, Gotschlich EC, Artenstein MS. Human immunity to the meningococcus. II. Development of natural immunity. *J Exp Med* 1969;129(6):1327-48, 1969 Jun 1.

### **MeNZB™ – Manufacture and ingredients**

- Jodar L, Feavers I, Salisbury D, Granoff D. Development of vaccines against meningococcal disease. *The Lancet* 2002;359:1499-1508.
- Frasch CE, Alphen Lv, Holst J, Poolman JT, Rosenqvist E. Outer Membrane Protein Vesicle Vaccines for Meningococcal Disease. In: Pollard AJ, Maiden MCJ, editors. *Methods in Molecular Medicine, Meningococcal Vaccines: Methods and Protocols*. Totowa NJ: Humana Press. p. 81-107.
- The Development of the NZ Meningococcal B Vaccine. Immunisation Advisory Centre, University of Auckland; 2004.
- Hem SL. Elimination of aluminum adjuvants. *Vaccine* 2002;20(Supplement 3):S40-S43.

### **Studies show group B vaccines work**

- Borrow R, Balmer P, Miller E. Meningococcal surrogates of protection--serum bactericidal antibody activity. *Vaccine* 2005;23(17-18):2222-2227.
- Wedege E, Hoiby EA, Rosenqvist E, Bjune G. Immune responses against major outer membrane antigens of *Neisseria meningitidis* in vaccinees and controls who contracted meningococcal disease during the Norwegian serogroup B protection trial. *Infection and Immunity* 1998;66(7):3223-31,.
- Boslego J, Garcia J, Cruz C, Zollinger W, Brandt B, Ruiz S, et al. Efficacy, safety, and immunogenicity of a meningococcal group B (15:P1.3) outer membrane protein vaccine in Iquique, Chile. *Chilean National Committee for Meningococcal Disease. Vaccine*. 1995;13(9):821-9.
- Tappero JW, Lagos R, Ballesteros AM, Plikaytis B, Williams D, Dykes J, et al. Immunogenicity of 2 serogroup B outer-membrane protein meningococcal vaccines: a randomized controlled trial in Chile.[see comment]. *Jama*. 1999;281(16):1520-7.

### **The MeNZB trials**

- Oster P, Lennon D, O'Hallahan J, Mulholland K, Reid S, Martin D. MeNZB[trademark]: a safe and highly immunogenic tailor-made vaccine against the New Zealand *Neisseria meningitidis* serogroup B disease epidemic strain. *Vaccine* 2005;23(17-18):2191-2196.

### **Safety first**

- Report of the Independent Safety Monitoring Board. 7 April 2005. Safety Monitoring Following MeNZB™ Immunisation 19 July 2004 – 27 February 2005

### **Further Evidence Based information is available from:**

#### **The Meningococcal B Epidemic**

- Annual reports and epidemic summary: National Reference lab, ESR (Environmental Science & Research Ltd) [www.esr.cri.nz](http://www.esr.cri.nz)
- Weekly updates on Ministry of Health web site [www.moh.govt.nz](http://www.moh.govt.nz)
- Regional epidemic information – contact local Public Health Units
- Published literature including *The Lancet* and *Vaccine Journals*

### **The Development and Manufacture of MeNZB™**

- The vaccine data sheet is available from Medsafe [www.medsafe.govt.nz](http://www.medsafe.govt.nz)
- Overview: Meningococcal information web site [www.immunise.moh.govt.nz](http://www.immunise.moh.govt.nz)
- Making of MeNZB™ article [www.immune.org.nz](http://www.immune.org.nz)
- Published literature on the Norwegian vaccine, The Cuban vaccine, Group b meningococcal vaccines and MeNZB™ available from Pubmed, including The Lancet and Vaccine Journals
- The manufacturer of MeNZB™ is Chiron Corporation: [www.chiron.com](http://www.chiron.com)

### **Safety of MeNZB™ & Outer membrane Protein (OMV) vaccines**

- CARM Centre for Adverse Reaction Monitoring, University of Otago <http://carm.otago.ac.nz/index.asp?link=carm>
- Meningococcal information web site [www.immunise.moh.govt.nz](http://www.immunise.moh.govt.nz) for detail on design of the safety monitoring programme
- Independent Safety Monitoring Board – for progress reports on the safety monitoring outcomes to date available from [www.immunise.moh.govt.nz](http://www.immunise.moh.govt.nz)
- Clinical Trial results summarised on [www.immunise.moh.govt.nz](http://www.immunise.moh.govt.nz) details available online from Pubmed, including The Lancet and Vaccine Journals, or researchers at University of Auckland & Norwegian Institute of Public Health

### **Efficacy of Meningococcal B and MeNZB™ vaccines**

- Summary of study designs to establish efficacy and effectiveness data : Plotkin Orenstein, *Vaccines* fourth Edition, Saunders, Pennsylvania 2004.
- Clinical trial results : summarised on [www.immunise.moh.govt.nz](http://www.immunise.moh.govt.nz) details available from Pubmed, including The Lancet and Vaccine Journals, or researchers at University of Auckland & Norwegian Institute of Public Health

### **Licensing of MeNZB™**

- Overview of standard medication licensing processes available from Medsafe [www.medsafe.govt.nz](http://www.medsafe.govt.nz)
- *New Zealand Gazette* Thursday, July 08, 2004 [www.medsafe.govt.nz](http://www.medsafe.govt.nz)
- *New Zealand Gazette* Thursday, February 03, 2005 [www.medsafe.govt.nz](http://www.medsafe.govt.nz)

### **Public Health Policy Decisions**

- Office of the Minister of Health
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