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Life is our life's work.

Pfizer New Zealand

18 October 2004

Ms Alice Lennon
Secretary
Immunisation Awareness Society Inc
PO Box 56 - 048
Dominion Rd
AUCKLAND

Dear Madam

Immunisation Awareness Society – Pamol®

I refer to the letter dated 21 September 2004 from the Executive Committee of the Immunisation Awareness Society ("IAS").

From the outset, I would like to reiterate Pfizer's primary concern in our original letter dated 26 August 2004. The IAS Statements and IAS Images clearly imply that:

- Use of Pamol® is one of the biggest risk factors for meningococcal meningitis.
- Pamol® should not be used for the treatment of babies or small children.
- Use of Pamol® in bacterial or viral infections prolongs infection and worsens the therapeutic outcome.
- Pamol® is harmful.
- The manufacturer of Pamol®, Pfizer New Zealand Ltd ("Pfizer") markets Pamol® inappropriately and harmfully.

A spokesman for the authors of the study (*Paediatric Infectious Disease Journal*, October 2000, Vol 19, No 10, 982-990), said that the study had been "wrongly interpreted; representations made by the anti-immunisation lobby were inaccurate and could mislead parents who may want to appropriately use a proven medication to reduce pain and fever in children with mild illness".

The spokesman said: "In the study, analgesic use itself was not attributed as a cause of Meningococcal disease and Pamol® was not even mentioned".

Pamol® or its equivalent brand name is marketed in many countries throughout the world, including Australia, South Africa, the United Kingdom and the USA. Pamol® has been marketed in New Zealand since the early 1980s. Pamol® (or its equivalent brand name) has been given marketing consent by the respective regulatory authorities after evaluation for safety, quality and efficacy. The approved indication is for relief of pain and reduction of fever in children and adults. As part of the regulatory process, an assessment of the labelling is undertaken to ensure that the labelling meets the requirements of the New Zealand Medicines Regulations 1984 and internal Medsafe Guidelines for paracetamol dosage. The Pamol® packs carry appropriate warning and cautionary statements as required by the Medicines Regulations.

These are:

- Do not give to children under 2 years of age except on medical advice; and
- Prolonged use can be harmful. Do not use for more than 48 hours without seeking medical advice.

Pfizer meets all regulatory requirements for the marketing of Pamol® in New Zealand. The advertising of Pamol® also meets the requirements of the Medicines Act and Regulations and the Code of Practice for the New Zealand Self Medication Industry, our industry body.

The health and safety of consumers is of utmost concern to Pfizer and we operate within the laws and regulations of the pharmaceutical industry in New Zealand.

In relation to the numerous questions that IAS has raised, Pfizer does not deem it necessary to address any of these.

IAS has misconstrued the demands made by Pfizer and removed them from context. For example, at no stage has Pfizer attempted to "prohibit use of the generic term 'paracetamol'" (see page 4 of IAS' letter); nor has Pfizer required that IAS "never use the term paracetamol at any time in the future, in anything [IAS] says, or publishes" (see page 5, question 1).

Pfizer maintains the position that the representations made by IAS are defamatory, detrimental to the goodwill and reputation of Pamol® and Pfizer, and are or are likely to be misleading or deceptive to consumers of Pamol® specifically and paracetamol generally. The various statements made by IAS clearly constitute direct medical advice to consumers not to use Pamol® in the treatment of their babies' and children's ailments. This is despite the fact that IAS claims (at page 17) that it "has never represented itself as being 'expert' in the medical field".

IAS also makes statements that in Pfizer's view, are grossly irresponsible, negligent and scandalous (for example, at page 10, question 12 – "that fever is rarely harmful and NOT TO TREAT FEVER with paracetamol…and that paracetamol makes disease worse, increases the death rate…; and at page 29, question 33 – "…why would Pfizer want anyone to be more likely to die by keeping a temperature down…?"; and at page 21 – "that 'paracetamol' used as an antipyretic is a risk factor which can, and does increase the severity of infection, and mortality, in all forms of bacterial meningitis"). In Pfizer's view, IAS is manifestly unqualified to make these statements.

In support of its arguments, IAS has cited a body of largely archaic references, many of which are of questionable scientific validity and lack a peer-review process, including website articles and questionnaires, media excerpts and other secondary sources, numerous of which are over 10, 20 and 30 years old. In the circumstances, we fail to see how IAS can purport to afford consumers "an informed choice" as it claims.

Pfizer reserves its rights in relation to the undertakings previously requested of IAS.

Yours faithfully

Peter Baltus
General Manager
Pfizer Consumer Healthcare