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Pfizer New Zealand

26 August 2004

The General Manager Immunisation Awareness Society Inc PO Box 56 - 048 Dominion Rd AUCKLAND

Dear Sir/Madam

IAS Claims that Pamol is a risk factor in meningococcal meningitis

I am writing to you in relation to statements published or caused to be published by your organisation ("IAS") in relation to Pamol® on your website, http://www.ias.org.nz/ (the "IAS Website").

IAS Representations

Statements

The following statements are published on your website:

"What are some of the biggest risk factors for meningococcal meningitis? ... Pamol"

"Not only does using pamol [sic] to reduce the fever just mask the symptoms, it actually stops the body doing what it is supposed to do. And it may increase the risk of meningococcal meningitis."

"DO NOT GIVE PAMOL TO CHILDREN AND YOUNG BABIES ..."

[at http://www.ias.org.nz/meningococcal_meningitis_info_july_2004.htm]

"Given that there are scores of medical articles which show that pamol [sic] should never be used for bacterial or viral infections, because it prolongs infection, and worsens the outcome, it is amazing that the medical profession still considers giving pamol [sic] for infectious fevers of any kind appropriate."

[at http://www.ias.org.nz/the_science_behind_a_no_decision.htm]

... "their [paracetamol manufacturers'] own literature has given enough warning to totally change the face of care of children with fevers, yet THEY HAVE DONE NOTHING to try and change parents perceptions on fever, or the use of paracetamol/Tylenol. And why is that? Follow the money. Over the counter antipyretics are the best money spinner there is. Wall Street Rules.

Again."

[under the link 'Paracetamol article from WAVES Vol 14 No 4' at http://www.ias.org.nz/menu26.htm].

You have also caused the following statement to be published in the Weekend Herald:

"Certain factors predispose to the arising of meningococcal disease, like ... use of pamol [sic]."

["Meningococcal Disease Scare" Advertisement, Weekend Herald, page A19, July 31 – August 1 2004]

(Collectively, the "IAS Statements")

Visual Representations

A picture of a bottle of Pamol Junior superimposed over an image of a gun (the "IAS Image") also appears on your website, under the headline "PARACETAMOL: MORE RUSSIAN ROULETTE FROM PUSHERS AND SHOVERS INC" [under the link 'Paracetamol article from WAVES Vol 14 No 4' at http://www.ias.org.nz/menu26.htm].

These statements constitute advertisements. Amongst other things, these advertisements compare Pamol® as a treatment for bacterial and viral infections with other treatments.

The IAS Representations

Cumulatively, the IAS Statements and the IAS Image suggest 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 Limited ("Pfizer") markets Pamol® inappropriately and harmfully.

(the "IAS Representations")

The IAS Representations Misrepresent Published Studies

The IAS Website relies on a study undertaken by the Wellington School of Medicine and published in the *Paediatric Infectious Disease Journal*, October 2000, Vol 19, No 10, 983 – 990 as support for its assertions that use of Pamol® is a major risk factor for meningococcal meningitis.

In a recent press release, a spokesman for the authors of the study said that the study has been "wrongly interpreted" by the anti-immunisation lobby. A copy of the press release is **attached** for your reference.

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

The spokesman said that the representations made by the anti-immunisation lobby were "inaccurate and could mislead parents who may want to appropriately use a proven safe medication to reduce pain and fever in children with mild illness".

The IAS Representations are misleading and deceptive

For the reasons set out above, the IAS Representations, communicated by the IAS Statements and the IAS Image, are unsubstantiated and do not accurately represent the situation. Further, the IAS Representations are misleading to consumers or are likely to mislead consumers. The IAS Representations are likely to have the effect of deterring parents from using Pamol® to reduce pain and fever in their children. The IAS Representations also have the effect of detracting from Pamol's goodwill and of otherwise detracting from Pamol's good name.

The IAS Representations are in breach of the Fair Trading Act

Section 9 of the Fair Trading Act 1986 (NZ) (the "FT Act") provides that no person shall, in trade, engage in conduct that is misleading or deceptive or is likely to mislead and deceive.

Section 10 of the FT Act provides that no person shall, in trade, engage in conduct that is liable to mislead the public as to the nature, characteristics or suitability for a purpose of goods.

For the reasons set out above, the IAS Representations are misleading.

The IAS Representations falsely suggest that use of Pamol® is one of the highest risk factors for meningococcal meningitis and that Pamol® should not be used in the treatment of children and babies. The IAS Representations therefore contravene Sections 9 and 10 of the FT Act.

The IAS Representations are defamatory

The IAS Representations defame Pfizer by suggesting that Pfizer inappropriately and unethically promotes the use of Pamol®.

The IAS Representations have or are likely to cause Pfizer monetary loss as well as loss of reputation and goodwill.

The IAS Representations are negligent

IAS holds itself out to be an authority on the issue of meningococcal meningitis and on the appropriate use and efficacy of Pamol®. IAS has not met the standards of care that would be expected of an expert in the medical field. By deliberately or negligently making false and misleading statements as to the relationship between Pamol® and meningococcal meningitis and the appropriate use of Pamol®, IAS has or is likely to cause harm to Pfizer and to parents who rely on the information provided by IAS in the treatment of their children.

The IAS Advertisements contravene the Advertising Standards Authority Code for Therapeutic Advertising

The references to Pamol® in the IAS Statements and the IAS Image contravene the Advertising Standards Authority Code of Advertising for Therapeutic Products ("the Code") as well as the advertising requirements of the *Medicines Act 1981*. Principles 2 and 3 of the Code state:

- "Advertisements should observe a high standard of social responsibility particularly as consumers rely on therapeutic products and services for their health and wellbeing."...
- "... advertisements should not by implication, omission, ambiguity or exaggerated claim mislead or deceive or be likely to mislead or deceive consumers, abuse the trust of or exploit the lack of knowledge of consumers, exploit the superstitious or without justifiable reason play on fear."

For the reasons set out above, the IAS Statements, the IAS Image and the IAS Representations are inaccurate and could mislead parents who may want to use a medication with a proven record of safety and efficacy to reduce pain and fever in children with mild illness. The IAS Statements and the IAS Representations do not observe the appropriate level of social responsibility for medical advertisements.

The IAS Representations constitute Trade Mark Infringement

Pfizer New Zealand Limited is the authorised user of Trade Mark 86513 for the word mark PAMOL. Section 94 of the *Trade Marks Act 2002* (NZ) provides that use of a registered trade mark in comparative advertising, otherwise than in accordance with honest practices in industrial and commercial matters, must be treated as infringing a registered trade mark if the use, without due cause, is detrimental to the repute of the trade mark.

Clearly, the IAS Representations are detrimental to the repute of Pfizer's registered trade mark.

Undertakings

As a consequence of the numerous breaches identified in this letter, Pfizer is suffering significant loss and damage. This loss and damage will continue if IAS does not provide the undertakings below to Pfizer.

Pfizer demands that IAS and its officers provide the following undertakings to it by no later than 5:00 pm on Wednesday, 1 September 2004:

- 1. IAS and its officers will immediately cease and forever desist from making or causing to be made the IAS Representations, or any representations which suggest that Pamol® or paracetamol is associated with the development of meningococcal disease.
- 2. IAS will immediately arrange the withdrawal of all current and planned advertising or other publications, which make the IAS Representations or which otherwise make misleading or deceptive references to Pamol®.

- 3. IAS will arrange, at its own expense, for corrective advertising to be placed in all publications in which the IAS Representations have appeared (including the IAS Website). This corrective advertising will be of the same size and prominence as the IAS Representations and must clearly detail the reasons why the IAS Representations are misleading and deceptive. Pfizer must approve the form and content of all corrective advertising in advance of publication.
- 4. IAS will provide a full schedule of all publications made or caused to be made by IAS (including but not limited to the IAS Website and newspaper advertisements) which contain or imply the IAS Representations or which otherwise refer to Pamol®.

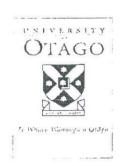
If you do not provide each and every one of the undertakings within the prescribed time, Pfizer will take such further action as it considers necessary to protect its interests without further notice to you, including (without limitation) by seeking urgent interlocutory relief against you. Pfizer reserves all of its rights in relation to the IAS Image, the IAS Statements and the IAS Representations.

Yours sincerely

Peter Baltus

General Manager

Pfizer Consumer Healthcare





19 July 2004

Study authors refute false claims by anti-immunisation lobby

Meningococcal disease researchers are today debunking claims made by the anti-immunisation lobby that linked Pamol with the disease.

Speaking on behalf of the authors of the study into risk factors for meningococcal disease, Dr Michael Baker from the University of Otago's Wellington School of Medicine and Health Sciences said the study published in 2000 in *The Pediatric Infectious Disease Journal* is being "wrongly interpreted".

"In the study, analgesic use itself was not attributed as a cause of meningococcal disease and Pamol was not even mentioned," Dr Baker said.

"The study found that a pre-existing respiratory infection increased the risk of meningococcal disease. Taking analgesics for the infection was one way of indicating that the child had a pre-existing infection.

"This makes sense as, of course, parents of an unwell child may rightly give the child an analgesic product. However, the analegesic then shows up as a marker to the disease when research like this is done."

Dr Baker believes the claims made by the anti-immunisation lobby are "inaccurate and could mislead parents who may want to appropriately use a proven safe medication to reduce pain and fever in children with mild illness."

"Although we know quite a bit about risk factors for meningococcal disease, it is not yet known why some people get this infection while most others do not."

Ends

For further information please contact Dr Michael Baker, Senior Lecturer, Wellington School of Medicine and Health Sciences, University of Otago

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