



PHARMACEUTICAL SOCIETY
of NEW ZEALAND
INCORPORATED

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Carol Smith
Secretary
Medicines Classification Committee
Medsafe
P O Box 5013
WELLINGTON

Dear Carol

**MEDICINES CLASSIFICATION COMMITTEE
AGENDA ITEM FOR 35th MEETING
SUBMISSION FOR RECLASSIFICATION OF IBUPROFEN**

This submission is a request to the Medicines Classification Committee to review the General Sale status of ibuprofen and remove the exemption currently in the Pharmacy Medicine classification – "except in packs containing 200 milligrams or less per oral solid dose form and not more than 25 dose units per pack in medicines which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and which are sold in the manufacturer's original pack".

Part A

1. Ibuprofen
2. All brands packaged for General Sale
3. Pharmaceutical Society of New Zealand Inc
4. All General Sale dose forms and strengths = ibuprofen when in packs containing 200 milligrams or less per oral solid dose form and not more than 25 dose units per pack in medicines which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and which are sold in the manufacturer's original pack
5. All General Sale pack sizes = ibuprofen when in packs containing 200 milligrams or less per oral solid dose form and not more than 25 dose units per pack in medicines which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and which are sold in the manufacturer's original pack
6. No change
7. General Sale for oral use in solid dose form containing 200 milligrams or less per dose form when in packs containing not more than 25 dose units and when in medicines which

have received the consent of the Minister or the Director-General to their distribution as general sale medicines and are sold in the manufacturer's original pack

8. Removal of the exemption from the Pharmacy Medicine classification of ibuprofen for oral use in solid dose form containing 200 milligrams or less per dose form when in packs containing not more than 25 dose units and when in medicines which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and are sold in the manufacturer's original pack.

9. Australia currently has the same General Sale exemption, but this will be challenged by the information contained in this submission.

UK is Pharmacy Medicine, with a General Sale exemption

USA has General Sale products, but with FDA warnings

10. Unknown

11. N/A

12. N/A

13. All brands of ibuprofen which have received the consent of the Minister or the Director-General to their distribution as general sale medicines

Part B

Next week the February issue of the Australian Journal of Pharmacy (AJP) will contain the attached article (embargoed until 7 February 2006) by Professor Greg Peterson from the Unit for Medication Outcomes Research and Education, at the School of Pharmacy, University of Tasmania. Professor Peterson has reviewed recent international literature and argues that ibuprofen is not suitable for many people. He describes new research on the cardiovascular, respiratory, gastrointestinal and obstetric risks of ibuprofen use that has emerged since the April 2004 decision to reclassify ibuprofen in New Zealand to permit the general sale of 200mg solid dose forms in approved packs of not more than 25 tablets.

These risks show the importance of ensuring the medicine is appropriate and safe for individual consumers. This cannot be done in a supermarket! A pharmacy is a much better place and a Pharmacy Medicine classification more suitable. Pharmacy staff and pharmacists are available there to ask questions, provide answers and advice on the quality use of ibuprofen.

At the time of the re-classification, Medsafe argued that there would be sufficient warning statements included in the 'approved' manufacturer's original pack. The Pharmaceutical Society believes such warnings are not sufficient because they rely on the consumer being able to read and understand them and be motivated to make the correct choices in relation to their own health needs and health risks. It is better that every sale be made under the guidance of a health professional.

We again reiterate what was in our 2003 submission, that the public in the main equates General Sale medicines to ones that are totally safe. Even although the package may carry warnings, the perception is that availability through supermarkets means the medicine is innocuous and does not require consideration of any risk factors. Within a pharmacy there is the opportunity for these issues to be raised and a sale refused if contra-indicated.

Next week, after the embargo is lifted, I will send you copies of the papers referred to in Prof Peterson's article. It is on the basis of these published papers that the Pharmaceutical Society requests the Medicines Classification Committee to review the General Sale status of ibuprofen and remove the exemption currently in its Pharmacy Medicine classification.

Yours sincerely

Euan Galloway

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Pharmaceutical Society of New Zealand (Incorporated)

P.S. Please note the embargo on Professor Peterson's AJP article until Tuesday 7th February 2006.