

18 May 2009

Medsafe Fees Consultation
Ministry of Health
PO Box 5013
WELLINGTON

Attention: Stewart Jessamine

Dear Stewart

RE: PROPOSED CHANGES TO FEES PAYABLE UNDER THE MEDICINES REGULATIONS 1984

The New Zealand Self Medication Industry Association is pleased to have the opportunity to respond to the document "*Proposed changes to fees payable under the Medicines Regulations 1984*". We will address the issues as laid out in the document of 15 April under the three main bullet points and we will make reference to each in turn:

1. *Medsafe intends to use the fee waiver mechanism provided for in the Medicines Regulations 1984 to reduce the fee for applications for approval of new innovative medicines and approval of clinical trials.*

NZSMI Response:

We are very comfortable with the concept of using the fee waiver mechanism provided in the Medicines Regulations 1984 to reduce the fee for applications for approval of new innovative medicines and approval of clinical trials. This particular clause relating to new innovative medicines and approval of clinical trials has little relevance for the NZSMI and therefore we will not comment other than to say that we are supportive of the fee waiver mechanism.

2. *Medsafe proposes to reduce its total fee revenue from new medicine and new related product applications by decreasing the number of instances in which fees apply.*

NZSMI Response:

The revised proposal for fee structure of new medicine applications appears to be much simpler in application than the current system and therefore we are generally supportive of its introduction- with the following amendments.

In the case where a separate strength, flavour or classification is submitted at a **different** time then the waivers used in the current system of fees should apply rather than the fees proposed, which generally are higher than those currently applied. Additionally, when an NMA is submitted at the same time then no additional fees should be payable for **additional** classifications. The reason for suggesting these amendments is that we do not believe any additional evaluator time is required and therefore there is no justification for the additional fees as proposed.

3. *Medsafe proposes to reduce total fee revenue from changed medicine and related product notifications by changing the way in which fees are applied.*

NZSMI Response:

After serious consideration, we are of the opinion that **the current system** with regard to CMN's should be retained. The new proposed fees and their application are such a complex and radical change from the current system that it is apparent that many companies will gain no benefit. Further, the new schedule is so different in its allocation of charges, that whether a company benefits or not appears to be purely by chance. We consider that the proposed changes favour notifications that contain a large number of changes and so could encourage some companies to combine unrelated applications with the sole purpose of effecting a reduction in fees. We question the desirability of encouraging such behaviour.

By way of example of the complexity of the new proposed system:

Firstly, there are "*some changes to when a CMN is required*" that in effect result in increased expense:

- (a) Category D – under "Excipient and finished product specifications" – The wording "*as a result of an updated monograph*" is not currently a notifiable variation and will in effect cause a significant increase in costs when compared with the current arrangement.
- (b) Category C – under the heading TSE Risk – "*Potential increase in the TSE risk status of any ingredient in the product*"- is also not currently notifiable and will therefore increase costs

Secondly, some current CMN changes are absent. We are unsure whether or not they will require a CMN going forward. Examples are:

- (i) Finished product testing sites;
- (ii) Over labelling sites;
- (iii) Changes to tablet shape.

This is not an exhaustive list but merely examples that we have noted.

Bulk Change

This issue is one, in our view, that needs to have special attention. We would propose that when a bulk change occurs that the '*Guidelines*' which allow for a fee waiver to apply are implemented. Both in the current and the new proposed fee schedule it appears this is not allowed. We believe it to be unfair for companies, who through a change of owner for example, can be required to pay significant fees for what are simple and repetitive changes.

Proposal

A mechanism for reducing the Memorandum Account could be to keep the existing fee structure and apply a 10% discount to each charge. The rationale for this is on the basis that there is \$1.14M in the memorandum account and this was collected over a period of 2 years from 2006. We understand that the total revenue achieved is in the region of \$11.4M and therefore it would appear 5% per annum has been collected as additional revenue. Applying a 10% discount over the next 2 years will bring about a correction and in our view is the fairest mechanism to achieve the objective so that companies who are submitting the largest

number of New Medicine Applications and Changed Medicine Notifications would benefit the most. Presumably, it is these companies that have also paid the most in the past, and so this proposal seems equitable.

As an alternative proposal -on the CMN fee structure, we would recommend that the \$400 fee for self assessable change notifications and additional products is reduced to \$200.

Summary

We have attached as Appendices information from 3 companies comparing the NEW and EXISTING schedules of fees. These have been determined by reviewing real submissions and using the two fee charges-both **current** and **new**. This further reinforces our point around the complexity and unfairness of the new CMN fee application process.

Conclusion

We welcome the fact that Medsafe is working to reduce the Memorandum Account and is attempting to do this as fairly as possible. On further investigation we have found that the new proposals, albeit well intentioned, do not appear to achieve that objective overall. We would suggest that the proposals that we have submitted are duly considered and if further consultation or discussion is required, we are willing to involve ourselves in that dialogue to bring about both the simplest and the fairest mechanism for all parties.

Thank you for the opportunity to be involved in the consultation process and we look forward to feedback to allow a mutually acceptable resolution

Yours sincerely

Tim Roper
Executive Director
New Zealand Self-Medication Industry Association

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APPENDIX 1

| Current CMN | Current Cost | Proposed CMN | Proposed Fee | |
|---------------------------|---------------------|---------------------|---------------------|-----|
| SL/ Storage G2 | 1600 | B | 1600 | NC |
| FP pack site G1 | 800 | C | 800 | NC |
| FP Spec Grade 5 | 800 | B | 1600 | Inc |
| Cont/closure/pack Grade 2 | 800 | B | 1600 | Inc |
| label Grade 2 | 800 | C | 800 | NC |
| Excipient Grade 2 | 800 | C | 800 | NC |
| trade name | 800 | C | 800 | NC |

APPENDIX 2

| DATE | CHANGE | CURRENT COST | PROPOSED COST |
|------------------|--|--------------|--|
| OVER THE COUNTER | | | |
| 7-Apr-09 | Formulation - Grade 1 Consequential change - excipient spec Consequential change - FP specs Consequential change - data sheet 2 products | 2000 | Cat B 1600 Cat C 800 Cat B 0 Cat D 0 Add prod 400 TOTAL 2800 |
| 2-Apr-09 | Indications/dosage - Grade 4 Labelling - Grade 1 2 products | 1200 | Cat C 800 Cat D 0 Add prod 400 TOTAL 1200 |
| 26-Mar-09 | FP Packing Site - Grade 2 FP specs/tests - Grade 5 | 2400 | Cat C 800 Cat B 1600 TOTAL 2400 |
| 26-Mar-09 | SACN - Labels | 400 | Cat D 400 |
| 26-Mar-09 | FP Specs/tests - Grade 5 | 800 | Cat B 1600 |
| 12-Mar-09 | Excipient specs/tests - Grade 2 | 800 | Cat C 800 |
| 12-Mar-09 | FP mnfg process - Grade 1 Consequential change FP specs 3 products | 2400 | Cat B 1600 Cat B 0 Add prods 0 TOTAL 1600 |
| 12-Mar-09 | FP mnfg process - Grade 1 Consequential change FP specs/tests Consequential change - FP mnfg, testing and packing site Indications/dosage - Grade 4 Labelling - Grade 1 | 2400 | Cat B 1600 Cat B 0 Cat A 2400 Cat C 800 Cat C 0 Cat D 0 TOTAL 4800 |
| 3-Mar-09 | Active Ingredient Mnfg site - Grade 3 Active Ingredient Specs/tests - Grade 3 FP specs/tests - Grade 5 2 products | 2800 | Cat C 800 Cat C 0 Cat B 1600 TOTAL 2400 |

| | | | | |
|-----------|---|--------|----------|--------|
| | | | Cat C | 800 |
| | Product name | | Cat C | 0 |
| | FP packing site - Grade 2 | | Cat D | 0 |
| | Container/closure/packaging - Grade 1 | | Cat C | 0 |
| | Indications/dosage - Grade 4 | | Cat D | 0 |
| | Data sheet - miscellaneous changes | | Cat C | 800 |
| 16-Mar | Labelling - Grade 2 | 4400 | TOTAL | 1600 |
| 22-Jan-09 | SACN - Data sheet | 400 | Cat D | 400 |
| 17-Dec-09 | NMA | 7650 | | 7650 |
| 17-Dec-09 | SACN - Labels | 400 | Cat D | 400 |
| 12-Nov-09 | SACN - Labels | 400 | Cat D | 400 |
| | | | Cat C | 800 |
| | Labelling - Grade 3 | | Add prod | 400 |
| 12-Nov-09 | 2 products | 1200 | TOTAL | 1200 |
| | | | Cat B | 1600 |
| | Formulation - Grade 1 | | Cat C | 800 |
| | Consequential change - excipient spec | | Cat B | 0 |
| | Consequential change - amended | | Add prod | 0 |
| | mnfg docs | | TOTAL | 2400 |
| 5-Nov-09 | 2 products | 1600 | | |
| 31-Oct-09 | NMA | 7650 | | 7650 |
| | | | Cat C | 800 |
| | Active ingredient specs/tests - Grade 3 | | Cat D | 0 |
| | Excipient specs/tests - Grade 1 | | Cat C | 0 |
| | Excipient specs/tests - Grade 2 | | Cat B | 1600 |
| | FP mnfg process - Grade 1 | | Cat B | 0 |
| 3-Nov-09 | Consequential change - FP specs | 3200 | TOTAL | 2400 |
| | | 42,100 | | 42,100 |

APPENDIX 3

| Product type | Details of change | Number of products | Current fees | Proposed fees |
|--------------|--|--------------------|-----------------|-----------------|
| Rx | New manufacturing site with consequential changes to formulation, excipient specifications, active ingredient specifications, finished product specs and packing site, container and labelling | 2 | \$7,600 | \$9,600 |
| Rx | New manufacturing site with consequential changes to active ingredient specs, excipient specs, batch size, packing site and datasheet | 4 | \$5,600 | \$7,200 |
| Rx + OTC | New packing site with updated packaging specs and labelling, datasheet | 3 | \$3,200 | \$2,400 |
| Rx | New packing site with updated packaging specs and labelling | 3 | \$2,800 | \$2,400 |
| OTC | Updated CEP and AI specs | 1 | \$800 | \$800 |
| OTC | New manufacturing site with consequential changes to AI specs, batch size, packing site, container, FP specs, labelling and excipient specs | 1 | \$4,000 | \$6,400 |
| | | | \$24,000 | \$28,800 |