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# **OTC Codeine Combinations**

**A submission to the 42<sup>nd</sup> meeting of the Medicines  
Classification Committee  
by the New Zealand Self-Medication Industry**

**September 2009**

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## Contents

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Executive Summary.....	3
Introduction.....	5
Effective use of codeine combination products .....	5
Misuse of codeine containing analgesics .....	6
Cold/flu/cough codeine-containing medicines.....	8
Defining the problem .....	8
Facing up to the issue.....	8
What solutions can be proposed? .....	9
Professional responsibility.....	10
Appendix 1 .....	11
Appendix 2 .....	15
Appendix 3 .....	17
Appendix 4.....	19

## Executive Summary

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- Analgesic codeine combinations play a very important role in the management of strong pain for a large number of consumers in New Zealand. They have been available without a prescription for many years. For the vast majority of users, they are effective and have an excellent safety profile.
- It is acknowledged that a very small number of people in New Zealand misuse or abuse analgesics containing codeine and have suffered serious adverse events as a result. However, the overwhelming majority of users benefit through appropriate and safe use.
- NZSMI believes that the needs and interests of the vast majority of responsible consumers need to be balanced against the risk of harm to a very small number of individuals. For responsible consumers, including the elderly and those who suffer with recurring episodic pain, e.g. musculoskeletal pain, the proposed restrictions would present unjustifiable difficulties in accessing quantities of analgesics to manage their pain.
- NZSMI is supportive of investigating a process, in conjunction with the Pharmacy Guild of New Zealand and the Pharmaceutical Society of New Zealand, that will look at how the sale of codeine combination products can be monitored more closely through pharmacy and those who could be purchasing excess quantities identified.
- NZSMI believes that cough and cold products containing codeine should be excluded from any consideration of measures aimed at addressing analgesic codeine combination issues. No evidence of inappropriate use has been identified in relation to these products. The theory that the problem of abuse/misuse would shift to cough/cold preparations, in the event of restrictions being imposed on analgesic combinations is entirely unfounded.
- NZSMI contends that restricting access to these products is unlikely to have any impact on the problem of addiction or abuse. Furthermore, it is uncertain what the potential unintended consequences of restrictions will have on the self management of pain in the community by a large proportion of the New Zealand public.
- NZSMI contends that the newly introduced joint code from the Pharmaceutical Society and Pharmacy Council of New Zealand on the sale of products of potential misuse and abuse should be allowed to take effect after its introduction in early 2009. Pharmacists have a clear understanding of their responsibilities in this area and along with the proposed initiative to investigate a means of monitoring customers who are excessively purchasing the products will go a long way to curb abuse and misuse.

- If, however, there is to be any change in the current scheduling then the NZSMI believes the following is a workable solution:-
  - (a) **Pharmacy only classification** for codeine combination products with 12mg or below of codeine base as a unit dose to a maximum 100mg daily dose and 7 days' supply.
  - (b) **Pharmacist restricted classification** for up to 15mg of codeine base as a unit dose with a maximum 100mg daily dose and more than 7 days supply but with a maximum pack size of a 100 tablets..
  - (c) **Prescription status** for 15mg and above of codeine base as a unit dose with no restriction on daily maximum or pack size.

*N.B 15mg of codeine phosphate is equivalent to 11.72mg of codeine base*

## Introduction

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The New Zealand Self-Medication Industry (NZSMI) welcomes the opportunity to comment on the agenda item for OTC codeine combination products for the 42<sup>nd</sup> meeting of the Medicines Classification Committee (MCC) in November.

NZSMI believes that without conclusive evidence to suggest otherwise, the current scheduling of OTC combination analgesics containing codeine provides an appropriate balance between access and the safe use of these medicines and thus should remain unchanged.

The vast majority of New Zealanders access codeine-combination products in a responsible manner. NZSMI does however acknowledge reports of a very small number of people who access and imbibe large quantities of analgesic codeine-combination products resulting in addiction or abuse. For those few, there is a solution to the problem. No scheduling change is required to solve this issue instead it requires the implementation of a monitoring approach at pharmacies and the full effect of the Code introduced early in 2009 around the selling, advertising and promotion of these products to consumers to take effect (see Appendix 1).

## Effective use of codeine combination products

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Moderate to severe pain is widespread in the New Zealand community. It is estimated that 1 in 5 New Zealanders suffer from persistent pain and most pain commonly occurs in older people. Effective management of acute or persistent pain should be a critical goal of any health system. The benefit of effective pain management includes greater productivity and improved quality of life. Therefore, any change to access of these medications will in turn impact on the quality of life and productivity for a great many in the community.

Effective management of pain in the community requires a multifaceted approach combining appropriate self-care (including self-medication) with support and advice from a wide range of healthcare professionals.

It follows that ready access to effective analgesic medicines is an important component of any community based pain management strategy. OTC codeine containing analgesics form an important self treatment option between simple analgesics and prescription strength products. The proportion of the New Zealand population who use OTC codeine containing analgesics is significant.

This highlights the significant extent of self management of moderate strong pain that occurs in the OTC setting. Research has shown that the number of days that people use OTC analgesic products per annum rises from an average of 45 days between the ages of 18-29 years up to an average of 90 days per annum between the ages of 60-75 years (Research carried out by GSK in 2006). Pack size restrictions will not solve the issue of misuse by the few, but will limit access by legitimate users. The availability of larger pack sizes provides consumers with a lower cost per dose unit particularly for the elderly and those who may be purchasing for a family. OTC codeine containing analgesics are widely

used, with the overwhelming proportion of use being appropriate and relevant to pain management needs of the consumer. This ongoing widespread use is also indicative of the benefit that consumers derive from OTC codeine containing analgesics.

## Misuse of codeine containing analgesics

The NZSMI believes that the numbers of those abusing codeine-containing analgesics is very small; this statement is made on the basis of an attempt to gain quantitative figures from various clinics and institutions in New Zealand – see the data below.

NZSMI believes that risk of harm can only be considered **high** in abusers of these products. It is very hard to find any evidence of potential harm to the general public associated with the use of OTC codeine analgesic products.

Centre for Adverse Reactions Monitoring (CARM) data.

Detailed below is a report from CARM for the period 2004 to July 2009.

Product	2004	2005	2006	2007	2008-2009	Total AE reports (2004-2009)	Total tablet sales (2004-2009)+	Total doses [2 tabs] (2004-2009)+	Total AE reports per 10 million doses (2004-2009)
Ibuprofen/Codeine Combination	2	0	2	0	0	4	106568300	53284150	0.8
Paracetamol/Codeine Combination	11	2	0	1	1	15	289412400	144706200	1.0
Codeine (non-OTC)	2	5	4	7	8	26	122463000	61231500	4.2

+ Source: IMS Data

Based on discussions with CARM (Janelle Ashton) the majority of AE reports pertaining to Paracetamol/Codeine are from use of CODALGIN, which is overwhelmingly obtained via doctor's prescription as a medicine under PHARMAC tender. To put this Paracetamol/Codeine CARM data into context it would appear that access to low cost codeine medicines via prescription seems to be a significant contributor to AE reporting, however this is not surprising given the large pack sizes supplied (100s) and volumes prescribed annually (414,100 packs). Significantly, these patients are under the care of a doctor and who are more likely to be reporting AEs. The fact that far fewer of these AE reports relate to actual 'OTC use' supports the Industry position that there is a lack of abuse of codeine containing analgesics.

Equally, importantly the rate AE reporting for OTC codeine combinations is extremely low at around 1 for every 10 million doses sold. This is significantly fewer than non-OTC Codeine products which are subject to AE reports of around 4 per every 10 million doses sold.

- For codeine analgesic combinations overall over this period, there were **no** reports of:
  - death
  - dependence
  - liver or hepatic complaints,
  - gastric bleeding, or
  - renal failure/impairment attributed to codeine-combination products

National Poisons Centre data.

Data from the National Poisons Centre over the period from 2003-2008 show extremely low numbers of abuse attributed to abuse of codeine-combination products (**See Appendix 3**).

Product 2003 - 2008	Reported abuse	Total reported contacts with NPC	Total doses (2 tabs) sold in a 12 month period*	No. of reported abuse incidents per 10 million doses consumed	No. of NPC Contacts per 10 million doses consumed
Ibuprofen / Codeine combination	2	154	50326850	0.40	31
Paracetamol/ Codeine combinations	2	805	138537400	0.14	58
Codeine (non-OTC)	4	795	54190250	0.74	147

\* Source: IMS Data MAT sales

Over this period, only 4 of 959 (<0.5%) reporting acute exposure to codeine-combination products were attributed to abuse; and to put this number further into context, that is of a very small number reporting an abuse event versus the volume of codeine-combination tablets sold over this period (fewer than 0.6 incidents per 10 million doses consumed). Critically, this is lower than the number of abuse incidents which are attributed to more tightly regulated non-OTC codeine products. This supports the view that restricting access would have little effect on abuse and may indeed drive abusers to higher strength products that would otherwise exacerbate what is presently a very small minority of people.

Pain and Addiction Clinic data.

The NZSMI has recently contacted a number of pain and addiction clinics across the country to obtain quantitative numbers of addicts or those abusing codeine-combination products – below is a table of the data.

	Evidence of abuse/addiction attributed to codeine-combination products	Quantitative numbers of abuse/addiction attributed to codeine-combination products
Capital Coast District Health Board Detox Clinics	Yes	10 over the last year
National Addiction Centre	Yes	very small; cannot quantify
Community Alcohol and Drug Services	Yes	very small; cannot quantify
Drug & Alcohol Services	Yes	very small; cannot quantify
Care NZ	Yes	very small; cannot quantify

In summary, the NZSMI has only been able to confirm 10 cases of codeine-combination product addicts over the last year in New Zealand. To put this in context, this represents 10 confirmed people of those who purchased 2.6 million OTC units of codeine-combination products in New Zealand over the last year. Considering the number of tablets sold to consumers via OTC and the number dispensed to patients via prescriptions this seems to us an infinitesimally small number of people addicted relative to intake.

## Cold/flu/cough codeine-containing medicines

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NZSMI does not consider any change to the scheduling status of these medicines as warranted: there is no evidence, even anecdotally, that they are used inappropriately. The suggestion that the problem of misuse or abuse would shift to cold/flu products if restrictions were to be imposed on analgesic codeine combinations is an untested hypothesis and therefore an inadequate basis for any regulatory intervention.

Furthermore, cold, flu and cough symptoms are acute in onset, self-limiting in duration, and when treated, do not require ongoing repurchase so potential ongoing abuse is mitigated.

It is noted that in Australia, NDPSC announced in their decision released in August

That *“the current scheduling of codeine combination products for cough/colds remained appropriate”*

## Defining the problem

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NZSMI believes that the crux of the issue is whether the potential for abuse of codeine containing products will be resolved through implementation of the currently proposed restrictive measures by the MCC.

NZSMI acknowledges reports of a very small number of people who access large quantities of analgesic codeine products, take them far in excess of recommended doses, and consequently then suffer severe adverse effects. There is no reason, however, to believe that restricting access to codeine containing analgesics will do anything to abate the problem of addiction.

## Facing up to the issue

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NZSMI believes that the needs and interests of the vast majority of responsible consumers need to be balanced against the risk of harm to a very small number of individuals, i.e. the risks and benefits associated with the use of OTC CACC having regard to the extent and patterns of use and the potential for its abuse. The NZSMI questions whether the proposed restrictions will achieve this balance. Non-prescription analgesics containing codeine are

essential in the self-management of pain in the community. We believe the proposed restrictions on access will not only disadvantage the many New Zealanders who use these medicines appropriately but will not help with the management of those who use them inappropriately. As shown in the IMS data at **Appendix 2** industry's estimate of the amount of codeine containing medicine used in New Zealand demonstrates that they are taken by a very large number of consumers.

***Appendix 2 is data for Codeine-combination products for the period MAT 20/7/09 for both units and dollars compared with the equivalent period a year earlier.***

It is well known that the analgesic use increases with age. It follows that a significant proportion of legitimate users are elderly. Others use these medicines mostly for intermittent episodic pain, e.g. musculoskeletal pain. The issue is to balance the legitimate needs and expectations of these many consumers against what harm might be mitigated to the very few.

NZSMI believes it would be reasonable to conclude that:

- the vast majority of New Zealanders use these medicines responsibly;
- there is evidence of a very few cases of abuse or misuse but the evidence is not sufficiently robust to extrapolate to population levels; and
- there is no indication of rising levels of misuse and/or adverse reactions which would suggest that the issue has become a public health issue of population level.

Drug addiction is a serious condition which requires medical intervention. It is extremely unlikely to be impacted in any way by limiting access to these medicines in pharmacies either by changing the status from pharmacy only or by only permitting access to smaller packs through pharmacist restricted classification. NZSMI believes that the proposed changes will not achieve the desired aims but adversely affect a large proportion of the New Zealand public.

## **What solutions can be proposed?**

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- There should be NO change to the current schedule for codeine-containing products in New Zealand; as a solution the potential misuse/abuse is able to be dealt with by pharmacist monitoring and educational campaigns.
- The proposed solution includes introduction of an online monitoring system for sales and allowing the Code promulgated by the Pharmacy Council and Society to gain traction after its adoption and introduction in early 2009.

If there is to be a scheduling change then NZSMI believes that a way forward should be:

1. To make available under the classification 'pharmacy only' codeine combination products with 12mg and below of codeine base as a unit dose to a maximum 100mg daily dose with 7 days' supply;
2. Pharmacy restricted classification up to 15mg of codeine base as a unit dose with a maximum 100mg daily dose and more than 7 days supply with a maximum pack size of a 100 tablets ;

3. Prescription status above 15mg of codeine base as a unit dose with no restriction on the daily dose or pack size.

The majority of pack sizes, 24's, 48's and 50's currently fall under the 7 days supply mandate. Any reduction from 7 days supply would add complexity to the market, increased cost to sponsors and may result in the loss of harmonised packs between Australia and New Zealand.

## Professional responsibility

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Attached as Appendix 1 is a joint document prepared by the Pharmaceutical Society of New Zealand (Inc) and the Pharmacy Council of New Zealand on the subject of ***The responsible sale of products of potential misuse and abuse***. This succinctly provides advice from the professional body's for pharmacy a Code for professionals in dealing with the sale of products of potential misuse and abuse. This was introduced in early 2009 and has been well received both by the industry and the profession of pharmacy. This approaches the issue in a responsible way rather than by disadvantaging the vast majority of the public who use these products responsibly. It needs to be given reasonable time to take effect in assisting the reduction of inappropriate use by counselling and monitoring sales of codeine combination products.

Finally, we have added as **Appendix 4** the "Medicines New Zealand" document, in particular the pages highlighting "*Optimal use: Medicines are used to their best effect*" segment. We believe this further reinforces our argument that the vast majority of people use medicines such as codeine containing products appropriately and in so doing find them safe and effective. We should not make changes that deny them that right.



### **Advertising to the Consumer and Promotion of Products of Potential Misuse**

Pharmacy staff have a professional responsibility when selling **codeine-containing and pseudoephedrine-containing preparations, and other medicines of potential misuse**. It is important that they continue to maintain a supply of such preparations for the legitimate user but they must exercise a high degree of professional supervision to ensure supplies do not find their way to misusers. This requirement must be taken into consideration when advertising and marketing these medicines. As a reminder, it is important to note that tolerance may develop on repeated use of codeine, while unintentional excess use may lead to morphine-type dependence.

Obligation 3.15 of the Pharmacy Council of New Zealand Code of Ethics requires pharmacists to exercise professional judgement to prevent the supply of any medicine, complementary therapy, herbal remedy or other healthcare product likely to constitute a hazard to health or the supply of unnecessary or excessive quantities of these, particularly those which the pharmacist knows or should reasonably be expected to realise are likely to cause or have a potential for misuse, abuse or dependency. Clearly the Code expects and requires a high standard of social responsibility for the promotion and sale of these medicines.

Obligation 8.2 places the responsibility on the Charge Pharmacist for the form and content of advertisements relating to that pharmacy whether personally placed or by another staff member or organisation on behalf of the pharmacy. The Charge Pharmacist is the pharmacist who is present in the pharmacy at any particular time and is responsible for the overall control of the provision of pharmaceutical services from that place.

Obligation 3.16 of the Code requires that medicines which the Charge Pharmacist knows or should reasonably be expected to realise are likely to cause or have a potential for misuse, abuse or dependency are not accessible to the public for self-selection, and in Obligation 3.18 the requirement is for these medicines to be stored and displayed in such a way that the pharmacist can exert supervision over their sale.

Examples of over the counter medicines that have an established misuse potential include:

- all codeine-containing preparations
- all pseudoephedrine-containing preparations
- opioids
- sedating antihistamines, sleeping aids, and travel sickness medication

- laxatives which may be misused by people with anorexia.

The Charge Pharmacist must use only those methods that are of a standard consistent with the professional image of pharmacy when advertising a medicine or other healthcare product (Obligation 8.3). The Code adds commentary to this provision:

**"In developing advertising and promotions the pharmacist must ensure that the emphasis or focus of the advertisement or promotion is benefits of the service, medicine, therapy or product other than its price.** It is to be noted that the responsibilities contained in this obligation extend to advertising materials supplied by manufacturers or other organisations such as banner and marketing groups."

Regardless of any promotional scheme the pharmacist must only sell, provide or promote the use of appropriate medicines in quantities appropriate to the clinical needs of the patient (Obligation 8.6).

The Charge Pharmacist must also ensure that advertisements or promotions do not promote misuse, injudicious or unsafe use or unnecessary or excessive use of any medicines (Obligation 8.7).

Finally, a pharmacist must only participate in promotional methods that do not encourage the public to equate medicines with ordinary articles of commerce (Obligation 8.4). This high standard reflects the special responsibilities and professionalism of health service delivery by pharmacists.

The full Code of Ethics can be downloaded from:

[www.pharmacycouncil.org.nz/cms\\_show\\_download.php?id=39](http://www.pharmacycouncil.org.nz/cms_show_download.php?id=39)

## Advertising Standards Authority

Advertisers should also be aware of the Therapeutic Products and Therapeutic Services Advertising Codes of the Advertising Code of the Advertising Standards Authority. These can be downloaded from [www.asa.co.nz/code\\_therapeutic\\_products.php](http://www.asa.co.nz/code_therapeutic_products.php) and [www.asa.co.nz/code\\_therapeutic\\_services.php](http://www.asa.co.nz/code_therapeutic_services.php).

Note that ASA Codes impose a high standard of social responsibility and in interpreting them emphasis is placed on the principles and the spirit of the Codes.

## Recommendations

As a result of these professional limitations, when advertising medicines of **potential misuse**, the following are recommended:

- Avoid self-selection or fish bowls; the products should not be displayed in any situation where the customer can self-select them, without supervision by staff. They should be displayed behind the counter on shelving close to the dispensary, and out of reach of the customer, where pharmacists can monitor the sale.
- Avoid dominant price stars. The price type should be no bigger than the type used for the product benefit or approved purpose.

- No incentives may be offered to purchase additional quantities.
- Special price coupons are not acceptable.
- Only smaller pack sizes should be advertised.
- Avoid competitions and associated special offers or gifts with purchase, even if there is no purchase necessary.
- Avoid company sponsored window display competitions for staff.
- Avoid price comparisons.

**It is permissible:**

- To use dummy boxes on the shelf for these products provided they are not bigger than the active product pack, so are not attracting attention.
- To have company posters or advertisements which do not mention price, on display in pharmacy, but not as a window display. Once price is mentioned this increases the promotional desirability for the product and is not appropriate that this be done in any way that is eye catching or likely to instigate a request for sale. The pharmacist has a professional duty to apply a very high standard for the sale of these products and must determine if the medicine is right for the consumer to purchase.

**Some pharmacists use the following statement for medicines with potential for abuse:**

The sale of this product will require discussion with a staff member to ensure safe and appropriate use and may require referral to a pharmacist. The sale may be recorded.

**The Self-Medication Industry Assn Code of Practice has further provisions:**

**from SMI Code Principle 3**

All medicine advertising and promotional activities must be prepared and executed with a high degree of social responsibility and shall conform to acceptable standards of competition. Advertisements and promotional activities shall not directly or indirectly encourage the indiscriminate, unnecessary or excessive use of any medicine.

**from SMI Code Principle 2**

Members shall not promote, or be in any way associated with, any scheme intended to encourage the sale of a non-prescription medicine if they are likely to introduce any hazard to the general public, or lower the tone of, or bring disrepute to the industry.

**from SMI Code Guideline 6.2**

An important part of the code is devoted to advertising and promotional activities with the prime focus on the need for a high degree of social responsibility in the preparation and execution of those activities.

**from SMI Code Guideline 6.3 Code of Conduct**

This Code of Conduct is to be read in conjunction with and as part of the industry code of Practice. It is to establish a common procedure for New Zealand manufacturers, marketers and distributors of non-prescription medicines to protect against the diversion of legitimate medicines, available primarily from pharmacy retail outlets, for the production of illicit drugs. It is considered inappropriate to offer specific sales incentives to pharmacy staff involving the sale of any products containing pseudoephedrine.

The full Code can be downloaded from [www.nzsmi.org.nz/CodeofPracticeJune06.doc](http://www.nzsmi.org.nz/CodeofPracticeJune06.doc)

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## Appendix 2

### IMS Data MAT to end July 2009 – Volume (Tablets)

#### C3 PROD SKU TABS

	MAT DEC/00 CU	MAT DEC/01 CU	MAT DEC/02 CU	MAT DEC/03 CU	MAT DEC/04 CU	MAT DEC/05 CU	MAT DEC/06 CU	MAT DEC/07 CU	MAT DEC/08 CU	MAT JLY/09 CU
N2A NARCOTIC ANALGESICS	8,002,200	9,566,900	9,954,000	11,194,700	13,080,900	16,457,500	20,604,800	23,064,200	23,978,400	25,277,200
<b>N2B NON-NARCOTIC ANALGESICS</b>	<b>40,609,900</b>	<b>45,215,300</b>	<b>48,360,700</b>	<b>55,009,800</b>	<b>58,888,000</b>	<b>64,011,900</b>	<b>66,901,100</b>	<b>69,864,300</b>	<b>73,587,000</b>	<b>72,636,300</b>
CODCOMOL	1,089,700	-	-	-	-	-	-	-	-	-
TABS 250MG 1200	1,089,600	-	-	-	-	-	-	-	-	-
TABS 250MG 50	100	-	-	-	-	-	-	-	-	-
CODALGIN	-	-	-	4,444,400	27,090,000	31,297,100	33,793,500	37,013,900	40,655,900	41,648,800
TABS 100	-	-	-	4,444,400	27,090,000	31,297,100	33,793,500	37,013,900	40,655,900	41,648,800
CODRAL	92,500	70,800	52,400	35,100	15,500	-	-	-	-	-
PAIN/REL TAB 20	23,900	17,200	8,700	6,500	3,300	-	-	-	-	-
PAIN/REL TAB 50	68,600	53,600	43,700	28,600	12,200	-	-	-	-	-
CODRAL FORTE	100	-	-	-	-	-	-	-	-	-
TABS 12	100	-	-	-	-	-	-	-	-	-
MERSYNDOL	1,751,000	1,980,800	2,056,400	1,958,100	2,021,600	1,974,300	1,620,600	1,520,300	1,438,700	1,332,400
TABS 20	1,751,000	1,980,800	2,056,400	1,958,100	2,021,600	1,974,300	1,620,600	1,520,300	1,438,700	1,332,400
<b>NUROFEN PLUS</b>	<b>3,763,100</b>	<b>6,236,300</b>	<b>9,504,800</b>	<b>12,476,100</b>	<b>15,048,700</b>	<b>17,088,600</b>	<b>17,627,200</b>	<b>18,746,400</b>	<b>18,209,100</b>	<b>16,533,800</b>
TABS 200MG 12	594,800	866,000	964,300	1,087,700	1,118,300	1,043,400	1,032,900	1,058,300	1,123,600	1,036,500
TABS 200MG 24	3,168,300	5,370,300	5,885,200	5,314,000	6,129,200	5,356,200	4,503,200	4,743,000	4,639,300	4,277,400
TABS 200MG 48	-	-	2,655,300	6,073,400	7,801,200	7,902,200	6,119,700	6,411,500	5,551,200	4,738,200
TABS 200MG 72	-	-	-	-	-	2,786,800	5,971,400	6,533,600	6,854,400	6,435,600
PREPACK 144	-	-	-	-	-	-	-	-	32,500	27,200
COUNTER UNIT 23	-	-	-	-	-	-	-	-	8,100	18,900
<b>PANADEINE</b>	<b>32,060,600</b>	<b>35,193,800</b>	<b>35,483,500</b>	<b>34,886,900</b>	<b>33,588,900</b>	<b>31,865,000</b>	<b>31,553,200</b>	<b>30,405,300</b>	<b>29,957,000</b>	<b>29,394,200</b>
TABS 12	298,700	305,900	277,600	289,300	236,500	183,600	200,800	164,400	174,200	99,500
TABS 24	3,038,900	3,151,700	2,892,000	2,869,800	2,252,600	1,726,900	1,552,100	1,366,900	1,211,800	1,187,700
TABS 50	4,120,900	4,539,200	4,425,200	4,863,700	4,750,500	3,901,400	3,620,700	3,278,800	2,961,900	2,767,100
TABS 100	2,589,500	2,931,600	3,116,400	4,057,400	4,883,700	4,998,100	5,070,300	4,545,500	4,361,900	4,077,700
TABS 500MG 1440	20,338,600	24,265,400	24,772,300	22,806,700	191,500	-	-	-	-	-
TABS 1000	1,674,000	-	-	-	-	-	-	-	-	-
CAPLETS 24	-	-	-	-	100	-	-	-	-	-
CAPLETS 48	-	-	-	-	-	100	600	-	-	-
CAPLETS 12	-	-	-	-	-	-	400	-	-	-
CAPLETS 24	-	-	-	-	561,800	332,600	360,500	319,500	386,100	382,500
CAPLETS 48	-	-	-	-	712,200	722,300	757,800	730,200	861,100	879,700
<b>PANAFEN</b>	-	-	-	-	-	-	-	-	1,458,600	1,855,900
PLUS CAPLETS 24	-	-	-	-	-	-	-	-	366,600	438,100
PLUS CAPLETS 48	-	-	-	-	-	-	-	-	1,092,000	1,417,800
<b>PANADEINE PLUS</b>	-	-	-	-	-	703,400	1,318,600	1,627,700	1,830,300	1,850,800
CAPLETS 500MG 12	-	-	-	-	-	703,400	1,318,600	1,627,700	1,830,300	1,850,800

## IMS Data MAT to end July 2009 – Value (NZD)

### ATC3 PROD SKU NZD

	MAT DEC/00 NZD MNF	MAT DEC/01 NZD MNF	MAT DEC/02 NZD MNF	MAT DEC/03 NZD MNF	MAT DEC/04 NZD MNF	MAT DEC/05 NZD MNF	MAT DEC/06 NZD MNF	MAT DEC/07 NZD MNF	MAT DEC/08 NZD MNF	MAT JLY/09 NZD MNF
N2A NARCOTIC ANALGESICS	786,557	1,013,337	1,113,012	1,367,307	1,531,074	1,740,916	2,152,356	2,368,642	2,123,997	2,229,113
N2B NON-NARCOTIC ANALGESICS	4,217,915	5,005,759	5,874,262	7,043,837	7,960,104	8,481,289	8,960,491	9,515,757	10,092,259	9,658,239
CODCOMOL	69,366	-	-	-	-	-	-	-	-	-
TABS 250MG 1200	69,352	-	-	-	-	-	-	-	-	-
TABS 250MG 30	6	-	-	-	-	-	-	-	-	-
TABS 250MG 50	8	-	-	-	-	-	-	-	-	-
CODALGIN	-	-	-	157,583	888,551	1,019,935	1,094,909	1,199,251	1,317,251	1,349,421
TABS 100	-	-	-	157,583	888,551	1,019,935	1,094,909	1,199,251	1,317,251	1,349,421
CODRAL	13,786	10,817	7,940	5,365	2,414	4	-	-	-	-
PAIN/REL TAB 20	4,889	3,676	1,909	1,426	731	4	-	-	-	-
PAIN/REL TAB 50	8,897	7,141	6,031	3,939	1,683	-	-	-	-	-
CODRAL FORTE	31	-	-	-	-	-	-	-	-	-
TABS 12	31	-	-	-	-	-	-	-	-	-
MERSYNDOL	405,351	501,215	540,181	559,075	628,782	632,772	519,410	487,263	461,098	427,042
TABS 20	405,351	501,215	540,181	559,075	628,782	632,772	519,410	487,263	461,098	427,042
MUROFEN PLUS	873,162	1,470,801	2,236,483	3,033,415	3,939,541	4,275,538	4,576,452	5,123,905	5,376,078	5,145,407
TABS 200MG 12	173,492	255,561	299,726	348,382	373,795	351,262	365,098	380,999	404,481	385,061
TABS 200MG 24	699,670	1,215,240	1,456,587	1,409,755	1,741,432	1,535,437	1,384,924	1,524,483	1,511,630	1,444,568
TABS 200MG 48	-	-	480,170	1,275,278	1,824,314	1,863,613	1,549,208	1,703,013	1,502,306	1,324,774
TABS 200MG 72	-	-	-	-	-	525,226	1,277,222	1,515,410	1,612,689	1,564,696
PREPACK 144	-	-	-	-	-	-	-	-	254,176	212,563
COUNTER UNIT 23	-	-	-	-	-	-	-	-	90,794	213,745
PANADEINE	2,338,652	2,532,630	2,723,997	2,942,050	2,181,311	1,947,672	1,926,664	1,835,966	1,852,238	1,773,437
TABS 12	73,438	75,208	77,960	86,799	70,952	57,233	63,682	55,160	58,806	33,579
TABS 24	517,876	537,105	565,460	597,880	469,290	373,327	342,120	321,480	299,063	294,956
TABS 50	505,223	556,507	623,738	730,530	713,525	608,416	576,408	555,993	535,891	518,359
TABS 100	287,176	325,114	396,447	550,587	662,717	704,270	729,876	696,168	700,460	659,774
TABS 500MG 1440	870,135	1,038,696	1,060,392	976,254	8,199	-	-	-	-	-
TABS 1000	84,804	-	-	-	-	-	-	-	-	-
CAPLETS 24	-	-	-	-	28	5	-	-	-	-
CAPLETS 48	-	-	-	-	8	16	98	-	-	-
CAPLETS 12	-	-	-	-	-	-	180	-	-	-
CAPLETS 24	-	-	-	-	132,260	78,302	82,321	76,943	95,458	94,995
CAPLETS 48	-	-	-	-	124,332	126,103	131,979	130,222	162,560	171,774
PANAFEN	-	-	-	-	-	-	-	-	235,292	297,378
PLUS CAPLETS 24	-	-	-	-	-	-	-	-	71,491	84,711
PLUS CAPLETS 48	-	-	-	-	-	-	-	-	163,801	212,667

## Appendix 3

### NATIONAL POISONS CENTRE DATA FROM 2003-2008

IBUPROFEN + CODEINE					
	Adult	Child	Unknown	Intent (total)	
2003	15	7	0	Abuse	2
2004	8	7	0	Child Exploratory	42
2005	20	9	0	Intentional	65
2006	22	7	0	Unintentional	43
2007	20	5	0	Unknown	2
2008	22	12	0		
PARACETAMOL + CODEINE					
	Adult	Child	Unknown	Intent (total)	
2003	88	36	0	Abuse	2
2004	79	44	0	Child Exploratory	253
2005	77	46	1	Intentional	346
2006	99	45	0	Unintentional	197
2007	88	45	0	Unknown	7
2008	114	43	0		
CODEINE					
	Adult	Child	Unknown	Intent (total)	
2003	70	33	0	Abuse	4
2004	39	53	0	Child Exploratory	302
2005	58	49	2	Intentional	316
2006	81	64	4	Unintentional	150
2007	80	85	1	Unknown	23
2008	104	72	0		

The above table contains a breakdown of the following:

Acute exposure calls to the National Poisons Centre 2003 – 2008

- Exposures to products containing ibuprofen + codeine by year and age
- Exposures to products containing paracetamol + codeine by year and age
- Exposures to products containing only codeine by year and age

Also included is the intent for each of these substance categories. These are the total for the period 2003 – 2008 for each substance and not broken down by year. The intent is divided into the following categories: Abuse, Child Exploratory, Intentional, Unintentional and Unknown.

NB: NPC only started distinguishing between abuse and intentional in 2007.

Definitions used:

- Abuse is defined as someone uses the substance in a way that it is not intended (e.g. they attempted to get high, they used it in a manner that it was not intended - they crushed and snorted it, deliberate ingestion but not for self-harm).
- Intentional is self-harm.
- Child Exploratory is when a child gets into the product and ingests it.
- Unintentional covers situations where the wrong dose may have been given, accidental double dose, incorrect strength or formulation, or any other accidental ingestion.

## Appendix 4

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### MEDICINES NEW ZEALAND

#### *Contributing to good health outcomes for all New Zealanders*

#### **Medicines New Zealand: Outcomes**

New Zealanders will have a medicines system that:

- delivers quality medicines that are safe and effective
- provides access to the medicines they need
- ensures that medicines are used effectively.

#### **Optimal use: medicines are used to their best effect**

Optimal use greatly influences the extent to which New Zealanders benefit from the therapeutic effects of medicines. Optimal use activities are crucial to ensuring that medicines that are assessed as being high-quality, safe and effective, are chosen, delivered and used in a way that ensures their potential to improve health and prevent illness is maximised. Optimal use activities also reduce wastage, enabling resources to be used more effectively.

Each of the three elements of *Medicines New Zealand* (quality, safety and efficacy; access; and optimal use) requires a commitment to collaboration between stakeholders and co-ordination of activities to achieve the desired outcomes. This is particularly true in the case of optimal use. Optimal use activities are diverse and are the responsibility of a wide range of people and agencies, including health practitioners and medicines consumers. Activities in this area also need good systems, for example, those envisaged by the Health Information Strategy for New Zealand (2005) and associated initiatives, to enable secure electronic transmission of information.

Behaviours and practices to support optimal use need:

- prescribers and other health practitioners to:
  - consider the most suitable and cost-effective treatment options, including non-medicinal and non-prescription alternatives
  - consider the safety and appropriateness (including the risks and benefits) of medicine choice in relation to clinical need
  - develop medicines plans that are mutually agreed with their patients
  - work collaboratively with other health practitioners and services to provide continuity of care and share up-to-date information on medicines risks and benefits and best practice treatment options
  - make services more available and provide treatment in a way that recognises the needs of individuals, including cultural differences
- medicines consumers to:
  - be active participants in their health management
  - be able to make informed decisions about medicines
  - understand the best way to use medicines (are 'health literate') and know where to go for information and support

- the medicines system to:
  - monitor and disseminate information to minimise the over-use, under-use, misuse and inappropriate disposal of medicines
  - provide effective regulation and post-market monitoring, in line with international best practice, to ensure ongoing assessment of medicines safety
  - have systems to support optimal medicines use practices, including safe medicines systems such as child-safe packaging and at-the-bedside medicines verification systems
  - monitor and evaluate the outcomes of medicines use.

Getting the best from medicines (optimal use) requires:

- robust medicines monitoring and reporting systems
- that consumers, health practitioners and medicines dispensers have access to timely and accurate information and education about medicines, how to take them and their use
- that prescribers have access to quality information about best practice treatment approaches
- that effective use is made of the skills of all health practitioners, as envisaged by the Health Practitioners Competence Assurance Act 2003
- that health providers (organisations and individuals) recognise that Maori and Pacific people may have specific perspectives and approaches to medicines use. To be effective, health services need to be whanau-inclusive and recognise specific attitudes and approaches to medicines use, including the use of traditional medicines such as rongoa Maori
- a collaborative and co-ordinated approach to ensure that optimal use activities are aligned and integrated across the medicines sector
- systems that make best use of electronic technology
- a culture of safety built on:
  - education for health practitioners and people using medicines
  - systems and technology to mitigate the impact of human error, including consideration of medicines safety practices for children
- that high-risk medicines and high-risk situations are identified and strategies enacted to minimise the likelihood of adverse events
- that special attention is given to the optimal use of antibiotics in light of the public health impacts of antibiotic resistance
- that particular attention is given to the interface between primary and secondary care services to ensure continuity of care and safe medicines use.

## *Optimal use*

### **Goal 11**

Information about medicines is collected and disseminated in a timely manner to ensure health practitioners and people using medicines have access to accurate, unbiased information and education about medicines, how to take them and their use.

### **Goal 12**

People using medicines take an active role in making decisions about, and managing, their health care. Medicines plans are mutually agreed with health practitioners.

### **Goal 13**

Robust and integrated systems support and monitor best-practice prescribing and the optimal use of medicines, including safe medicines use practices.

### **Goal 14**

Maori and Pacific people receive health care services that meet their needs, are whanau-inclusive and recognise their specific attitudes and approaches to medicines use, including the use of rongoa Maori.