Submission to the Medicines Classification Committee for the Reclassification of Ibuprofen in Liquid Sachet Unit Dose Forms

30 July 2012

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Executive Summary

The current classification for a liquid ibuprofen 200 mg unit dose sachet, with a maximum daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation, and when sold in the manufacturer's original pack containing not more than 25 dose units is 'Pharmacy Only' Medicine.

The equivalent products in a tablet, capsule or powder unit dose form are 'general sale'.

Reckitt Benckiser wishes to be able to market ibuprofen in New Zealand (subject to approval by Medsafe) in liquid-filled sachet unit dose forms under the same classification rules that currently apply to divided solid dose forms. This will require amendments to the 'general sale' and 'pharmacy only' classifications as follows (proposed amendments underlined):

General Sale
Ibuprofen in divided solid or liquid forms for oral use containing 200 milligrams or less per dose form, with a recommended daily dose of not more than 1.2 grams, when labelled for adults and children 12 years and over, and when sold in the manufacturer's original pack containing not more than 25 dose units.

Pharmacy Only
For oral use in *undivided* liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use in solid *or liquid* dose forms containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; except in divided solid *or liquid* dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams, when labelled for adults and children 12 years and over, and sold in the manufacturer's original pack containing not more than 25 dose units

The proposed amendments for ibuprofen are in line with the current 'general sale' classification of a powder dosage form of ibuprofen, paracetamol and aspirin.

A US survey[1] in 2004 has revealed that 40% of adults have experienced difficulty swallowing pills, even though most have had no problems swallowing food or liquid. About twice as many women (51%) as men (27%) experienced pill-swallowing problems. More people between ages 8 and 64 reported having these problems (44%) than those aged 65 and older (26%). This finding is expected to be similar to adults in

[1] PR Newswire Jan 15, 2004 40% of American Adults Report Experiencing Difficulty Swallowing Pills; National Survey Shows Many Failed to Take Medication as Directed Because of Difficulty Swallowing Pills.

New Zealand. In addition to providing consumers with more choice this finding supports the need for an alternate dosage form other than tablets or capsules.

A summary of the data in support of this application is as follows:

[redacted]

- packs of ibuprofen 200 mg tablets, caplets or liquid capsules of up to 25 dosage units have been available for patient self-selection supermarkets for a number of years in both Australia and New Zealand..

[redacted]

[redacted]

- When the re-classification of ibuprofen 200 mg tablets or liquid capsules of up to 25 dosage units from Pharmacy Medicine to General Sale Medicine was sought in 2004, data on trends analysis over time, safety monitoring/pharmacovigilance data as well as published meta-analyses and company-sponsored clinical studies the medical literature did not reveal any increased reporting rates of adverse reactions following reclassification to Pharmacy Only Medicine[2]. The status quo has remained for the past 9 years.

- There are a number of alternative aspirin and paracetamol in powder, granule or dispersible tablet forms already available as General Sale medicines in New Zealand.

- This dose form will provide more choice for consumers:

    - who are unable to swallow a solid dosage form

[2] http://medsafe.govt.nz/profs/class/MedIbupReview.asp Medsafe Advice on MCC recommendation on ibuprofen.

- where paracetamol is contraindicated, e.g. hypersensitive, hepatic impairment
- who prefer a liquid oral dosage form.

- Factors such as ability to easily transport their pills (80%), ease of administration (78%), and no need for preparation (76%), followed by no need for water when swallowing pills (65%) and better taste of the pill (61%) are important in the decision of the majority of people with swallowing problems who are unsure or somewhat likely to try other dosage presentation[1]. Ibuprofen liquid in sachets can offer these consumers convenience as it can be:

  - easily transported
  - presented in a ready-to-use sachet
  - no water is required

- The proposed classification for divided dose forms of liquid ibuprofen is not expected to increase the potential risk of adverse events nor the potential for abuse or misuse.

Part A

A.1 International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

Ibuprofen

A.2 Proprietary name(s)

Proposed:
NUROFEN ibuprofen 200 mg/10 mL (2%) Suspension, 10 mL sachets.
NUROFEN ibuprofen 400 mg/10 mL (4%) Suspension, 5 mL sachets.

A.3 Name of company/organisation/individual requesting reclassification

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A.4 Dose form(s) and strength(s) for which a change is sought

Liquid oral suspension in sachets each containing 200mg ibuprofen

A.5 Pack size and other qualifications

Up to 25 dose units, restricted to adults and children 12 years and older, as General Sale Medicine,
Up to 100 dose units as Pharmacy Only Medicine.

A.6 Indications for which change is sought

No change is sought in relation to indications. The current approved indications for ibuprofen products in New Zealand are: Temporary relief of pain and/or inflammation associated with headache, migraine headache, tension headache, muscular pain, cold & flu symptoms, period pain, dental pain, sinusitis, back pain, arthritic pain. Reduces fever.

A.7 Present classification of medicine

The current classification for ibuprofen according to Medsafe's database[3]:

Table 1: Current NZ Classification for Ibuprofen

Ingredient	Conditions (if any)	Classification
Ibuprofen	except when specified elsewhere in this schedule	Prescription
Ibuprofen	for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; except in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units	Pharmacy Only
Ibuprofen	for external use; in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack	General Sale
Ibuprofen	for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age	Restricted

A.8 Classification sought

The classification requested for ibuprofen in liquid form for adult use is from Pharmacy Only Medicine to General Sale Medicine as follows:

Table 2: Proposed Re-classification for ibuprofen in New Zealand

Ingredient	Conditions (if any)	Classification
Ibuprofen	except when specified elsewhere in this schedule	Prescription
Ibuprofen	for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use *in divided* solid *or liquid* dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; except in divided solid *or liquid* dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams *when labelled for adults and children 12 years and over,* and when sold in the manufacturer's original pack containing not more than 25 dose units	Pharmacy Only
Ibuprofen	for external use; in divided solid *or liquid* dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams *when labelled for adults and children 12 years and over,* and when sold in the manufacturer's original pack containing not more than 25 dose units per pack	General Sale
Ibuprofen	for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age	Restricted

[3] http://www.medsafe.govt.nz/profs/class/classification.asp

A.9 Classification status in other countries (especially Australia, UK, USA, Canada)

The classification status of the proposed dosage form in other countries is:

Australia[4]

ibuprofen 200 mg/10 mL (2%) Suspension, 10 mL sachets
ibuprofen 400 mg/10 mL (4%) Suspension, 5 mL sachets

are General Sale in packs of up to 25 dose units.

UK[5]
Ibuprofen 200 mg/10 mL (2%) and 400 mg/10 mL (4%) suspension in sachets are Pharmacy Medicine.

Canada[6]
Ibuprofen 200 mg/10 mL (2%) and 400 mg/10 mL (4%)suspension, in packs of up to 45 sachets are GSL.

US[7]
Ibuprofen in suspension formulation for adult use has not been marketed OTC, but the children's formulations have been marketed OTC since 1998.

A.10 Extent of usage in New Zealand and elsewhere (e.g. sales volumes) and dates of original consent to distribute

The Nurofen brand of ibuprofen (as acid, sodium dihydrate, lysine) has been available in New Zealand from as early as 1984. Most of the formulations have been replaced by new formulations and currently, the following Nurofen General Sale Medicine products are:

Table 3: Nurofen General Sale Medicine Products on Medsafe Register

Product Name	**TT50-**	**Date of Consent**	**Marketed**
Tablet			

Nurofen Coated tablet, 200mg	1377/2b	8/07/2004	Yes
Nurofen Back Pain Film coated tablet, 342mg	6251/2	6/12/2007	Yes
Nurofen Caplet Coated tablet, 200mg	1377/10b	8/07/2004	Yes
Nurofen Lysine Film coated tablet, 342mg	7958	25/10/2007	No
Nurofen Migraine Pain Film coated tablet, 200mg	6251a	8/07/2004	Yes
Nurofen Period Pain Film coated tablet, 342mg	7901	15/03/2007	Yes
Nurofen Rapid Film coated tablet, 342mg,	7963	29/11/2007	No
Nurofen Tension Headache Film coated tablet, 200mg	7481	29/09/2005	Yes
Nurofen Zavance Caplets Coated tablet, 256mg	1377/15	18/12/2008	Yes
Nurofen Zavance Tablets Coated tablet, 256mg	1377/14	18/12/2008	Yes
Orodispersible tablet			
Nurofen Meltlets Lemon Orodispersible tablet, 200mg	6628a	21/12/2006	No
Nurofen Meltlets Mint Orodispersible tablet, 200mg	6628b	21/12/2006	No
Liquid Capsule			
Nurofen Zavance Liquid filled capsule, 200mg	1377/18	10/12/2009	Yes
Nurofen Liquid Liquid filled capsule, 200mg	1377/11a	8/07/2004	Yes

Other brands of ibuprofen available as General Sale medicines include the following:

Table 4: Other ibuprofen Products on Medsafe Register

Product Name	**Date of Consent**
Act-3 Liquid filled capsule, 200mg	21/07/2005
Advil Coated tablet, 200mg	6/07/2006
Advil Liquid filled capsule, 200mg, Liquid capsules	24/03/2011
Advil Mini Caps Coated tablet, 200mg	13/07/2006
Codral Cold & Flu Sore Throat Tablet, with ibuprofen	23/06/2011
Ibuprofen Coated tablet, 200mg, Home Brand	22/01/2009
Ibuprofen Coated tablet, 200mg, Medix	22/01/2009
Ibuprofen Film coated tablet, 200mg, (Signature Range)	13/01/2005
Ibuprofen Film coated tablet, 200mg, Ethics Range	4/11/2004
Ibuprofen Film coated tablet, 200mg, Pams	29/09/2005
Ibuprofen Film coated tablet, 200mg, Rex, (Capsule shaped)	28/08/2008
Ibuprofen Liquid filled capsule, 200mg, Medix	26/11/2009
Ibuprofen Liquid Capsules Liquid filled capsule, 200mg, Ethics	2/12/2010
i-Profen Film coated tablet, 200mg	13/01/2005
Maxigesic Film coated tablet, 500mg/150mg	5/03/2009
Panafen IB Film coated tablet, 200mg	8/07/2004

[redacted]

[redacted]

Table 5: [redacted]

[redacted]

The Nurofen brand of ibuprofen is also registered in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, France, Greece, Hungary, Ireland, Israel, Italy, Malta, Netherlands, Poland, Portugal, Romania, Russia, Saudi Arabia, South Africa, Spain, Switzerland, Thailand Ukraine and the UK. In the US ibuprofen first became available as OTC in 1984. Over 90 billion 200-mg tablet doses were sold between 1984 to 1996 and this number has substantially increased since. [redacted]

A.11 Labelling or draft labelling for the proposed new presentation(s)

The proposed liquid sachet products will be labelled with the same directions for use, indications and warning statements as the equivalent solid dose forms (tablets, caplets and liquid capsules) currently marketed in New Zealand, with the additional restriction of being labelled for use in adults and children over 12 years.

A.12 Proposed warning statements if applicable

The proposed liquid sachet products will be labelled with the same warning statements as the equivalent solid dose forms (tablets, caplets and liquid capsules) currently marketed in New Zealand, with the additional restriction of being labelled for use in adults and children over 12 years.

A.13 Other products containing the same active ingredient(s) and which would be affected by the proposed change:

A search for ibuprofen products on the Medsafe site conducted on 2 April 2012 showed that there are currently 12 registered ibuprofen in the tablet form and 3 products are in liquid capsule form that are General Sale Medicines[8].

Table 6: Ibuprofen products on Medsafe Register that will be affected by the proposed scheduling change

Products	Sponsor	Date of Consent
Advil Liquid filled capsule, 200mg, Liquid capsules (General sale)	Pfizer New Zealand Limited	24/03/2011
Ibuprofen Liquid filled capsule, 200mg, Medix (General sale)	Nova Pharmaceuticals NZ Limited	26/11/2009
Ibuprofen Liquid Capsules Liquid filled capsule, 200mg, Ethics (General sale)	Multichem NZ Limited	2/12/2010
Maxigesic Film coated tablet, 500mg/150mg (General sale)	AFT Pharmaceuticals Ltd	5/03/2009
Panafen IB Film coated tablet, 200mg, General sale (General sale)	GlaxoSmithKline (NZ) Ltd	8/07/2004
Panafen IB Caplets Tablet, 200mg (General sale)	GlaxoSmithKline (NZ) Ltd	8/07/2004
Ibuprofen Film coated tablet, 200mg, (Signature Range) (General sale)	Multichem NZ Limited	13/01/2005
Ibuprofen Film coated tablet, 200mg, Ethics Range (General sale)	Multichem NZ Limited	4/11/2004

i-Profen Film coated tablet, 200mg (General sale)	Multichem NZ Limited	13/01/2005
Ibuprofen Coated tablet, 200mg, Home Brand (General sale)	Nova Pharmaceuticals NZ Limited	22/01/2009
Ibuprofen Coated tablet, 200mg, Medix (General sale)	Nova Pharmaceuticals NZ Limited	22/01/2009
Advil Coated tablet, 200mg (General sale)	Pfizer New Zealand Limited	6/07/2006
Advil Mini Caps Coated tablet, 200mg (General sale)	Pfizer New Zealand Limited	13/07/2006
Ibuprofen Film coated tablet, 200mg, Pams (General sale)	REX Medical Ltd	29/09/2005
Ibuprofen Film coated tablet, 200mg, Rex, (Capsule shaped) (General sale)	REX Medical Ltd	28/08/2008

The proposed change will give consumers a choice of selecting a dose form that will meet their needs; as with paracetamol, there are currently more choices - 18 products in tablet form, 8 products in capsule form and 25 products in powder form.

Part B

B.1 A statement of the benefits to both the consumer and to the public expected from the proposed change

The proposed liquid product will benefit adults and children 12 years and over who have difficulty in swallowing tablets or capsules or who would prefer to have their medicines in a liquid dose form. It will also provide consumers with a greater choice since there are no ibuprofen liquid unit dosage products available in New Zealand.

An online survey of 679 adults (513 aged 18-64 years, 166 aged 65 years and older) in the US[1], revealed that a large percentage (40%) of American adults have experienced difficulty swallowing pills, even though most have had no problems swallowing food or liquid. About twice as many women (51%) as men (27%) experienced pill-swallowing problems, and interestingly, more people between ages 8 and 64 years reported having these problems (44%) than those aged 65 and older (26%). Most people that had problems taking pills described the sensation as having a pill stuck in their throat (80%), having a bad after taste in their mouth (48%), or gagging (32%). This finding is expected to be similar for adults in New Zealand.

The classification of ibuprofen in liquid form in convenient sachet packs from Pharmacy Only Medicine to General Sale Medicine will provide an alternate dosage form for consumers:

- who are unable to swallow a solid dosage form
- where paracetamol is contraindicated, e.g. hypersensitive, hepatic impairment
- who prefer a non-solid oral dosage form.

B.2 Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated

The epidemiology study by James et al 1991[9] on a sample of 1498 adults aged 18-64 years, confirmed that most people (66% to 93%) have experienced pain at some time in their life which was sufficiently serious to see a health-professional, use medication, or to interfere with daily activities. Pain was most common in the joints, back, head, and abdomen. Women reported more pain than men.

In the 2002/2003 New Zealand Health Postal Survey[10] on 540 adults on the general electoral registers showed that 50.7% [40.0% (women < 40 years) to 66.7% (women older than 65 years)] for musculoskeletal pain lasting at least 7

days in the last month. The pain was associated with a reduction in health related quality of life (at least as severely as people with diabetes, ischaemic heart disease, chronic liver disease and cancer).

Pain may be a significant cause of distress for the majority of the population at some point in their lifetime, it can be easily self-diagnosed and self-medicated.

The above information demonstrates that pain is a very common complaint and that consumers would be able to self-diagnose and self-treat their complaints without consultation with a GP.

The Health Information for New Zealanders'[11] website provides information to consumers about the different types of pain, namely muscular, dental, arthritic, headache, migraine, inflammatory conditions as a result of common cold or flu, tooth extraction and fever are easily identified complaints and the options available for managing pain. Pain relief medication is one of the segments where information is available for consumers. The website acknowledged that "pain relief medications and anti-inflammatories have become more easily available - supermarkets have allowed more types to be purchased directly (over-the-counter), and prescription pain relief manufacturers are also coming up with new options your doctor might prescribe". Information on the differences between analgesics and anti-inflammatories, their main benefits and the main risks associated with it are also available. It also asserted that the advice on the packaging of over-the-counter medications, can be relied upon to reduce the risks associated with taking these medications and that the risks are small, and do not pose a threat to everyone who uses these forms of pain relief.

Ibuprofen in divided solid and powder dose forms have already been classified 'General Sale' and 'Pharmacy Only' Medicines, and undivided liquid ibuprofen 'Pharmacy Only'. The proposed amendment to the scheduling will make ibuprofen available to consumers in a convenient liquid dose form.

The same indications and restrictions that currently apply to tablets, caplets and liquid capsules will apply to the proposed unit dose liquid form.

B.3 Relevant comparative data for like compounds

B.3.1 OTC criteria for other analgesics

Paracetamol and aspirin are already accepted as 'General Sale' and 'Pharmacy Only' in tablet capsule and unit dose powder forms. Paracetamol is accepted as 'Pharmacy Only' medicine in undivided liquid dose forms (see Table 8).

Table 7: OTC Criteria of paracetamol and aspirin in Australia & New Zealand

New Zealand
• Paracetamol: in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; in powder form in sachets containing 1 gram or less and not more than 10 grams classified General Sale.
• Aspirin: except when specified in the First Schedule to the Medicines Regulations 1984 (Restricted - in slow-release forms; in enteric coated forms containing more than 300 milligrams per dose form; except when specified elsewhere in this schedule; Prescription - for injection; when combined with caffeine, paracetamol, or salicylamide) are 'General Sale'
Australia
• Paracetamol in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and /or guaiphenesin or when combined with effervescent agents) when: o enclosed in a primary pack that contains not more than 12 such powders or sachets of granules; o compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; o not labelled for the treatment of children 6 years of age or less; and o not labelled for the treatment of children under 12 years of age when o combined with phenylephrine and/or guaiphenesin; are 'General Sale' medicines (unscheduled).
• Aspirin in individually wrapped powders or sachets of granules each containing 650 mg or less of aspirin as the only therapeutically active constituent other than an effervescent agent when: o enclosed in a primary pack that contains 12 or less such powders or sachets o of granules; and o compliant with the requirements of the *Required Advisory Statements for* o *Medicine Labels*; are 'General Sale' medicines (unscheduled)..

B.4 Local data or special considerations relating to New Zealand

Over the past 20 years, ibuprofen has gradually moved from prescription medicine to lower levels of classification, including general sales status from 2004. There is no evidence to suggest that increased consumer access has led to the emergence of consumer safety issues[2].

An epidemiology study by James et al 1991[9] on a sample of 1498 adults aged 18-64 years, confirmed that most people (66% to 93%) have experienced pain at some time in their life which was sufficiently serious to see a health-professional, use medication, or to interfere with daily activities. Pain was most common in the joints, back, head, and abdomen. Women reported more pain than men.

The proposed changes to the classification for ibuprofen will give New Zealand consumers the same access to divided dose liquid ibuprofen products as they currently have for ibuprofen tablets and capsules. This will be a

positive benefit for people who have difficulty swallowing tablets or capsules or who would simply prefer to take medicines in a liquid form.

Furthermore, pain is a common experience in the general population and it is costly both for the individual and for health services. Access to a remedy in a suitable and convenient dosage form should not be denied.

B.5 Interactions with other medicines

Having divided liquid dose forms on ibuprofen in the 'General Sale' medicine schedule, with the same restrictions as for divided solid dose forms and undivided liquid dose forms, will not change the risk of interactions with other medicines.

B.6 Contraindications

The same contraindications that currently apply to the 200 mg tablet, caplet and liquid capsule of ibuprofen/Nurofen products will apply to the proposed liquid sachets as follows:

- Allergic to ibuprofen, aspirin or other anti-inflammatory medicines. If they should have an allergic reaction, to stop taking and to see their doctor immediately.
- Last three months of pregnancy
- Stomach ulcer or other stomach disorders.

The label also cautions:

- consumers to seek medical advice if they are taking medication regularly and if they are over the age of 65 years
- consumers not to take the product for more than 3 days at a time, except on their doctor's advice. The recommended dose should not be exceeded and excessive use can be harmful
- consumers not to take the product during the first 6 months of pregnancy, except on their doctor's advice.

In addition the liquid sachets will be contraindicated for children under 12 years.

B.7 Possible resistance

Not applicable

B.8 Adverse events - nature, frequency etc

Divided dose forms of liquid ibuprofen are likely to have the same level of adverse events as divided solid dose forms and undivided liquid dose forms.

The PAIN study[12] which used GPs to identify and enroll patients with painful conditions for allocation to treatment with either: aspirin, paracetamol or low dose ibuprofen used exclusion criteria based on the warning statements normally included on the products. There was a total of 1108 GPs, which included 8677 adult patients (2900 aspirin, 2886 ibuprofen, 2888 paracetamol). The study demonstrated that the safety profile for all products was excellent and that amongst those patients without a past history of ulcer disease, low dose ibuprofen was less likely to cause a stomach problem than either aspirin or paracetamol.

Data on consumer testing on the labelling of other ibuprofen products were previously considered by MCC[2]. These data demonstrated that a majority of patients read the label of OTC products when first using the product and that the warning statements proposed for the product were both readable and understandable by more than 80% of a representative sample of potential users of the product.

Given the above safety data and warning statements on the label, adverse effects with non-prescription (OTC) short-term use ibuprofen are rare.

B.9 Potential for abuse or misuse

Ibuprofen has a very low to absent potential for abuse or misuse as supported by its General Sales status[2].

Ibuprofen has been readily available in many countries for several years as an OTC product. A literature search conducted for this application has not been able to locate reports of abuse or misuse associated with products containing ibuprofen.

The proposed changes to the classification of ibuprofen to a General Sale Medicine are not expected to increase the potential for abuse or misuse.

References

1. PR Newswire Jan 15, 2004. 40% of American Adults Report Experiencing Difficulty Swallowing Pills; National Survey Shows Many Failed to Take Medication as Directed Because of Difficulty Swallowing Pills.

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3. http://medsafe.govt.nz/profs/class/classification.asp
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9. James FR, Large RG, Bushnell JA & Wells E. Epidemiology of pain in New Zealand. Pain 44 (1991): 270-283

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13. Periodic Safety Update Report from 1 October 2008 to 28 February 2011 (Appendices not included but available upon request)