SUBMISSION FOR THE RECLASSIFICATION OF A MEDICINE

Guaiphenesin Modified Release Tablets

30 July 2010

EXECUTIVE SUMMARY

The 41st meeting, held 14 May 2009, of the Medicines Classification Committee (MCC) recommended a change to the scheduling of Guaiphenesin in a modified release dose form as follows:-

"That guaiphenesin should be reclassified from prescription medicine to general sale medicine when:

> *pack size is limited to not more than 5 days' supply*
> *in a modified release dosage form*
> *a maximum daily dose of not more than 2400 mg is recommended*
> *sold in packs approved by the Minister or the Director-General for distribution as general sale medicines.*

That guaiphenesin should be reclassified from prescription medicine to restricted medicine when:

> *pack size is more than 5 days' but not more than 30 days' supply*
> *in a modified release dosage form*
> *a maximum daily dose of not more than 2400 mg is recommended*
> *sold in packs approved by the Minister or the Director-General for distribution as restricted medicines.*

That Medsafe should be satisfied with data supporting efficacy, and with the proposed label warnings, of any modified release guaiphenesin product seeking consent to be sold as an OTC medicine. "

Following this the 43rd MCC meeting, held 13 April 2010, considered an application by Medsafe to reclassify 4 active ingredients in Cough & Cold medicines. The MCC concluded that "the risk benefit assessment supported the current classification of guaiphenesin" and that the current classification therefore remained appropriate.

Therefore the scheduling of Guaiphenesin currently includes General Sales, Restricted Medicine and Prescription Medicine but no Pharmacy Only classification.

Reckitt Benckiser welcomes both recommendations from the MCC. However, there are some limitations with the current classifications and we now seek further changes to the scheduling and warnings for modified release Guaiphenesin, as follow:

- Include an additional classification, limited by pack size, as a Pharmacy Only Medicine
- Amend the labelled warning statement to seek medical advice if symptoms persist from 'after three days' to 'after 5 days'
- Remove the labelled warning regarding a potential risk of developing kidney stones at high doses

Information in support of these changes is provided in Part B of this submission.

PART A

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

Guaiphenesin (British Approved Name); guaifenesin (US adopted name). Also known as glyceryl guaicolate, guaiphenesin, guaicol glycerol.

2. Proprietary Name

MUCINEX®

3. Name of company/organisation/individual requesting reclassification

Reckitt Benckiser (New Zealand) Ltd
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Henderson, Auckland

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

Modified release tablets of 600mg or 1200mg guaiphenesin

5. Pack size and other qualifications

2, 20, 40, 60,100 tablets

6. Indications for which change is sought

Expectorant – thins and loosens mucus (phlegm) to help relieve chest congestion.

7. *Present classification of medicine*

Conditions (if any)	Classification
for oral use in medicines containing 2% or less or 200 milligrams or less per dose form; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing not more than 5 days supply approved by the Minister or the Director-General for distribution as a general sale medicine	General Sale
for oral use in medicines containing more than 2% or 200 milligrams per dose form except when specified elsewhere in this schedule; except for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing not more than 5 days supply approved by the Minister or the Director-General for distribution as a general sale medicine	Prescription
for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing more than 5 days supply but not more than 30 days supply approved by the Minister or the Director-General for distribution as a restricted medicine	Restricted

8. *Classification sought*

Conditions (if any)	Classification
for oral use in medicines containing 2% or less or 200 milligrams or less per dose form; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing not more than 5 days supply approved by the Minister or the Director-General for distribution as a general sale medicine	General Sale
for oral use in medicines containing more than 2% or 200 milligrams per dose form except when specified elsewhere in this schedule; except for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing not more than 5 days supply approved by the Minister or the Director-General for distribution as a general sale medicine	Prescription
for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing more than **10** days supply but not more than 30 days supply approved by the Minister or the Director-General for distribution as a restricted medicine	Restricted
for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams sold in a pack containing more than 5 days supply but not more than **10** days supply approved by the Minister or the Director-General for distribution as a Pharmacy medicine	Pharmacy Only

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

The classification of Guaiphenesin is currently under review in many of these countries and has recently been reviewed by the MCC at their 41st and 43rd meetings. For these reasons the information has not been repeated here.

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

Detailed information was provided in our submission to the 41st MCC meeting. This information will have had little change so has not been repeated in this submission.

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

Please refer to the labelling attached for Mucinex 600 mg.

12. Proposed warning statements if applicable

Please refer to the labelling attached for Mucinex 600 mg.

The recommendation of the 41st MCC meeting was that the labelling include a warning regarding the potential to develop kidney stones at higher doses and to seek medical advice if symptoms persist after three days.

This application seeks removal of the requirement for a warning regarding the potential for the development of kidney stones. The supporting data for this request is included in the attachment titled “Response to Medicines Classification Committee. - Stimulant-associated guaifenesin urolithiasis and warning limits”.

The same document also discusses the need for a 3 day limit before seeking medical advice and supports the addition of a Pharmacy Only classification.

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

The proposed change in scheduling will not affect the classification of any other currently registered guaiphenesin medicines.

Part B

Reasons for requesting classification changes

This section should be supported where relevant by the following:

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

The current General Sale and Restricted Medicine classifications will provide acceptable access to Mucinex®. However the demands on a Pharmacists time as a result of a Restricted Medicine classification may limit the availability of Mucinex®. Providing a Pharmacy Only classification, in addition to the current classifications, will allow self-selection by the consumer while still under the control of the Pharmacist and Pharmacy staff

This will provide consumers with ready access to a proven effective sustained cough relief product without the need to visit a doctor for a prescription or to have personal details recorded by the Pharmacist. This will reduce the strain on the healthcare system while promoting self-care.

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

Colds are one of the most common illnesses. An average person will have at least one cold per year[1]. The flu is similar, and sometimes has the same symptoms as a cold but is often much more severe and lasts longer. Cold and flu viruses attack the upper respiratory tract including the nose, nasal sinuses, throat, trachea and bronchi. They invade the moist lining of these structures and can cause a runny nose, sinus congestion, sneezing, sore throat and cough. Other typical symptoms include malaise and tiredness.

Since cold and flu are quite common, the symptoms are easily diagnosed by either the sufferer or a pharmacist. A productive cough may be the last symptom left after a cold or flu. Coughs are often worse when waking and when talking. Patients may feel congested and breathless, with the cough bringing up mucus or phlegm[2].

Statistics from the UK[3] presented at the recent Australian Self-Medication Industry Annual Conference in November 2008 by Fabian Dwyer, General Manager IMS Australia & New Zealand support that coughs and colds are considered minor ailments and comprise only 3.4% of the visits in a general practice. Since 50.5% of these patients do not receive a prescription for

[1] http://quickcare.org/resp/colds.html
[2] http://www.mydr.com.au/respiratory-health/cough-productive-or-wet-cough
[3] Fabian Dwyer. Driving the Self Care Agenda: Minor Ailment Workload in General Practice, Presentation ASMI Conference 19 November 2008.

treatment, most patients with coughs are left to either seek advice from the pharmacies or self-medicate.

The symptoms have been adequately managed by the patients with rest, adequate hydration and self-selected decongestants and cough medicines[3].

3. Relevant comparative data for like compounds

Detailed information was provided in our submission to the 41st MCC meeting. This information will have had little change so has not been repeated in this submission.

4. Local data or special considerations relating to NZ

The proposed reclassification would increase consumer's access to a convenient, portable and long-lasting form of treatment for chesty coughs.

The addition of a Pharmacy Only classification for the modified release tablets would benefit New Zealand consumers by providing ready access to larger pack sizes of an effective sustained release cough relief product.

5. Interactions with other medicines

There are no reported interactions with other medicines.

6. Contraindications

The following warnings are included on the proposed CMI for Mucinex®, currently with Medsafe for evaluation.

"Guaiphenesin is contraindicated for use in persons with known hypersensitivity or idiosyncratic reaction to guaiphenesin (or any of the other ingredients in the product).

Guaiphenesin has been shown to be porphyrinogenic in animals and should not be used in persons with porphyria.

Guaiphenesin should not be used for chronic or persistent cough associated with chronic lower respiratory tract diseases such as asthma, bronchitis, chronic obstructive pulmonary disease (COPD), emphysema or smoker's cough."

7. Possible resistance

Not applicable

8. Adverse events – nature, frequency etc

The safety and efficacy of modified release Guaiphenesin (Mucinex®) has been evaluated and approved by Medsafe. It has also been reviewed recently by the MCC at their 41st and 43rd meetings.

The issue of overdose and the potential for developing kidney stones is discussed in detail in the attached document "Response to Medicines Classification Committee. - Stimulant-associated guaifenesin urolithiasis and warning limits".

Reckitt Benckiser seeks removal of the MCC's requirement for this warning. If approved, the CMI will be amended accordingly.

9. Potential for abuse or misuse

Guaifenesin is not recognised to have any abuse potential.

SUMMARY OF CHANGES SOUGHT

Information provided in this submission and its attachments seeks consideration of the following changes by the Committee:-

- Include an additional classification, limited by pack size, as a Pharmacy Only Medicine
- Amend the labelled warning statement to seek medical advice if symptoms persist from 'after three days' to 'after 5 (or 7) days'
- Remove the labelled warning regarding a potential risk of developing kidney stones at high doses

REFERENCES

Please note that a full set of references was supplied with our application to the 41st MCC meeting. This application only includes new references relevant to this submission, ie 4-6

1	http://quickcare.org/resp/colds.html
2	http://www.mydr.com.au/respiratory-health/cough-productive-or-wet-cough
3	Fabian Dwyer. Driving the Self Care Agenda: Minor Ailment Workload in General Practice, Presentation ASMI Conference 19 November 2008.
4	Mucinex labelling – including kidney stones warning
5	Mucinex proposed CMI
6	Response to medicines classification Committee – Stimulant-Associated Guaifenesin Urolithiasis and warning Limits.