Codeine Scheduling Changes 1 May 2010

BE PREPARED – Part 1 & 2

Background
Over recent years there has been growing concern over the misuse of combination analgesics containing codeine. Misuse has occurred through the use of codeine as an adjunct to drugs of abuse and by people who become dependent on chronic pain medication. In particular, adverse consequences due to overuse of products containing ibuprofen in combination with codeine have been reported, including reports of perforated gastric ulcers and renal failure with long term use. This issue has been monitored by the National Drugs and Poisons Schedule Committee (NDPSC). At its meeting held in October 2009, the NDPSC made a final decision to change the scheduling of these products to assist in addressing this issue.

From 1st May 2010, tighter controls will apply to the Over-The-Counter (OTC) availability of analgesic products containing codeine (see below). The availability of cold and flu products containing codeine will be unaffected by the change.

Current Scheduling of Codeine Containing Analgesics
Codeine-containing analgesic products are currently available OTC as Schedule 2 (Pharmacy Only) and Schedule 3 (Pharmacist Only) products, according to strength and pack size. In general terms, smaller pack sizes containing lower amounts of codeine per dosage unit are captured under Schedule 2, and higher strength and/or larger packs are captured under Schedule 3. Well-known brands include Nurofen Plus® and Panafen Plus® (codeine-ibuprofen), Panadeine® (codeine-paracetamol) and Aspalgin® (codeine- aspirin).

New Scheduling – Effective 1 May 2010
As of 1st May 2010 analgesic products containing codeine:

- will not be available under Schedule 2 (Pharmacy Only)
- which contain up to 5 days treatment with a maximum dosage unit of 12mg codeine (15.4mg codeine phosphate), will be available under Schedule 3 (Pharmacist Only)
• in larger pack sizes (ie greater than 5 days’ treatment) and higher strengths of codeine (ie greater than 12 mg codeine/15.4mg codeine phosphate) will only be available by Prescription.

These changes will have an impact on the day-to-day operations of all community pharmacies which will need to prepare in advance of the change. The Scheduling changes will have both professional and stock management implications.

How to prepare for the change

Professional preparation

All pharmacy staff including pharmacy assistants will need to become familiar with the new restrictions so as to be in a position to explain the change to their customers. Staff should also brush up on their knowledge of effective pain management strategies, including non-drug options to be used either alone or as an adjunct to medication.

Pharmacists should be in a position to demonstrate an up-to-date working knowledge of Quality Use of Medicines issues and the place in therapy of codeine containing analgesics, including an ability to effectively counsel patients in their use of pain relievers. Paracetamol remains the initial treatment of choice for most forms of chronic pain, with non-steroidal anti-inflammatory drugs (NSAIDS) as second-line if paracetamol alone is not adequate. Useful references to assist pharmacists to update their knowledge are provided below.

Staff should also review the PSA Professional Standards (Standards for the provision of Pharmacy medicines and Pharmacist Only medicines in community pharmacy www.psa.org.au) and the relevant standards in the Quality Care Pharmacy Program (2nd Edition).

Suggested references include:

3. Therapeutic Guidelines - Analgesic; 2007
Additional information is available through the Royal Australian College of General Practitioners (RACGP) [www.racgp.org.au](http://www.racgp.org.au) and the National Health and Medical Research Council (NHMRC) [www.nhmrc.gov.au](http://www.nhmrc.gov.au)

**Stock management preparation**

Sponsor companies are in the process of manufacturing stock in order to comply with the new regulations in time for the implementation date of 1\textsuperscript{st} May 2010. They have already ceased production of the older stock, but these products may still be in circulation at the time of the change. In order to assist companies during this transition period, State/Territory Health Departments have indicated that they will grant labelling exemptions to manufacturers so as to allow the continued supply and use of remaining ‘old’ stock leading up to and after the change. Newly packaged stock may also be available before the change. Such stock will also be exempted for labelling purposes as a practical way of dealing with the change during this transition period.

This will mean that community pharmacies may be receiving a mixed supply of ‘old’ and ‘new’ stock throughout 2010. The labelling exemptions to enable old stock to be supplied by the wholesaler and pharmacies will expire on 31 December 2010 and pharmacists should bear this in mind in their purchasing processes.

It is important to be aware that, although there will be exemptions for labelling purposes, these exemptions will NOT apply for storage and supply purposes. This means that pharmacies, irrespective of the packaging and labelling of products supplied by the wholesaler MUST abide by the scheduling changes from the day of implementation ie 1\textsuperscript{st} May 2010. Thus all analgesic products containing codeine will need to be located within the pharmacy according to Schedule 3 requirements and only the allowable pack sizes (see above under ‘New Scheduling’) will be able to be kept in the Schedule 3 Medicines area of the pharmacy and sold without a prescription. Any remaining larger pack sizes (ie those containing more than 5 days’ supply) must be moved to the dispensary and supplied based on a prescription only.

It is suggested that pharmacies are particularly careful in their purchasing of larger pack sizes leading up to the change and that they discuss their needs and any stock return policies with their wholesaler and/or the manufacturer.
Pharmacy Guild Support material

The Pharmacy Guild of Australia will be providing detailed information in the coming months to support the profession to adapt to the changes in a streamlined manner in order to minimise any disruptions to the business and customers. The Guild has been working with manufacturers to ensure all support materials developed provide accurate, up-to-date and consistent information.

Guild materials are currently under development and will include fact sheets to be used as a reference tool for staff within the pharmacy in the lead up to the change. Information will also be available on the Guild Website www.guild.org.au from March 2010. Readers should refer to these materials and have them available to assist staff and customers with the transition.

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From 1 May 2010, tighter controls will apply to the non-prescription availability of analgesic products containing codeine. This article continues on from the initial information provided in the February/March 2010 Edition and is intended to assist pharmacists to inform pharmacy staff to prepare for the changes.

**New Scheduling – Effective 1 May 2010**

Packs of combination analgesics containing codeine in divided preparations (e.g. tablets or capsules):

- will **not be available** as *Pharmacy Medicines* (S2)
- will be *Pharmacist Only Medicines* (S3) when:
  - containing up to 5 days’ treatment and up to 12 mg codeine per dosage unit, and
  - labelled with a recommended total daily dose of up to 100 mg codeine
- will be *Prescription Only Medicines* (S4) when:
  - containing more than 5 days’ treatment **and/or** greater than 12 mg codeine per dosage unit, or
  - labelled with a recommended total daily dose of more than 100 mg codeine

In addition, combination analgesic products containing codeine:

- cannot be advertised directly to the consumer
- in undivided preparations (e.g. mixtures) will be *Pharmacist Only Medicines* (S3) when they contain up to 5 days’ treatment **and** 0.25% or less of codeine **and** are labelled with a total daily dose of up to 100 mg codeine (e.g. Painstop for Children® Day-Time Pain reliever).

Currently available cold and flu products containing codeine are unaffected by the change.
How existing* products are affected by the change

<table>
<thead>
<tr>
<th></th>
<th>Before 1 May 2010</th>
<th>After 1 May 2010</th>
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<tbody>
<tr>
<td><strong>Pharmacy Medicines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(S2)</td>
<td>Nurofen® Plus and other brands 12, 24 units (48 units in NSW)</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>Panadeine® and other brands 10, 16, 20, 24 units (up to 100 units NSW only)</td>
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</tr>
<tr>
<td></td>
<td>Aspalgin® and other brands 20 units (up to 100 units NSW only)</td>
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<tr>
<td><strong>Pharmacist Only Medicines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(S3)</td>
<td>Nurofen® Plus and other brands 48 units (except NSW), 96 units</td>
<td>Nurofen® Plus and other brands 12, 24 units‡</td>
</tr>
<tr>
<td></td>
<td>Panadeine® and other brands 50 and 100 units (except NSW)</td>
<td>Panadeine® and other brands 10, 16, 20, 24 units‡</td>
</tr>
<tr>
<td></td>
<td>Aspalgin® and other brands 48, 50, 100 units (except NSW)</td>
<td>Aspalgin® and other brands 20 units‡</td>
</tr>
<tr>
<td></td>
<td><strong>Panadeine® Extra and other brands 12 units</strong></td>
<td><strong>Panadeine® Extra and other brands 12 units‡</strong></td>
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<tr>
<td></td>
<td><strong>Mersyndol® and other brands 20 units</strong></td>
<td><strong>Mersyndol® and other brands 20 units‡</strong></td>
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<tr>
<td><strong>Prescription Only Medicines</strong></td>
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<tr>
<td>(S4)</td>
<td>Panadeine® Forte and other brands 20 units</td>
<td>Panadeine® Forte and other brands 20 units</td>
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<tr>
<td></td>
<td></td>
<td>Nurofen® Plus and other brands 48 tabs, 96 units</td>
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<td>Panadeine® and other brands 50 and 100 units</td>
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<tr>
<td></td>
<td></td>
<td>Aspalgin® and other brands 48, 50, 100 units</td>
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</tbody>
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* Products existing as of February 2010
‡ The new arrangements will mean that under the Pharmacist Only Medicine (S3) schedule:

- products with a daily dose of 6 units (e.g. Nurofen® Plus) may come in packs of up to 30 units
- products with a daily dose of 8 units (e.g. Panadeine®) may come in packs of up to 40 units

New pack sizes may be available. For more information, contact the company representatives.

Preparing for the Change
It is important that pharmacists and their staff are aware of the impact these changes will have on their pharmacy practice and are prepared to manage this impact.

1. Stock Management
   - In order to monitor the level of stock you will require, it is recommended that you take these products off automatic reordering and make sure that pharmacy staff who are responsible for any manual ordering, understand the changes. Particular consideration needs to be given to the larger pack sizes (more than 5 days’ supply) as these will become Prescription Only Medicines (S4) from 1 May 2010 and you don’t want to be left with stock that you cannot readily sell.

   - There will be a transition period until 31 December 2010 during which State/Territory Health Departments have indicated that they will grant labelling exemptions to manufacturers so as to allow the continued supply and use of remaining ‘old’ stock, as well as any ‘new’ stock that becomes available, leading up to and after the change. During this time, the schedule included on the pack may not match the product’s actual scheduling status. It is important that staff fully understand that the exemptions apply to labelling only and not to storage or supply.

   **During the transition period, irrespective of labelling, stock must be stored and supplied according to the scheduling arrangements current at the time.**
2. **Pharmacy workflow and staff levels**

From 1 May 2010, there will be much more stock in the *Pharmacist Only Medicines* (S3) section of the pharmacy and it would be reasonable to anticipate greater demands on the time of the pharmacist.

Before 1 May, it is important to:

- Review your pharmacy’s storage location for *Pharmacist Only Medicines* (S3) in preparation for the significant increase in the number of products to be stored there.
- Review your pharmacy’s procedures for the sale of *Pharmacist Only Medicines* (S3) and assess whether this can be streamlined.
- Ensure that pharmacy assistants in the scheduled medicines area have had the appropriate training.
- Plan adequate staffing levels in order to manage any change in pharmacy workflow and to support the pharmacist having more involvement in the front-of-shop.

3. **Advertising**

Codeine is not included in Appendix H of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and therefore combination analgesics containing codeine cannot be advertised from 1 May 2010. This includes advertising such as TV, radio, catalogues, posters and in-store promotion. Make sure any of your pharmacy’s advertising or promotional materials (including price lists) are in line with the Therapeutic Goods Advertising Code available from [www.tgacc.com.au](http://www.tgacc.com.au)

4. **Quality Use of Medicines**

Thorough preparation for the change, both from the stock management and professional perspectives will be fundamental to ensuring the Quality Use of these products.

Pharmacists should be in a position to demonstrate an up-to-date working knowledge of Quality Use of Medicines principles and the place in therapy of combination analgesics containing codeine, including an ability to effectively counsel patients in their use of pain relievers. Some useful websites include:

- [www.nps.org.au](http://www.nps.org.au)
As for the provision of any Pharmacist Only Medicine, the pharmacist has a duty of care and professional obligation to do their best to ensure the patient understands the harms and benefits of the codeine analgesics. Therapy should be tailored for the individual patient taking into account the condition being treated, contra-indications and potential drug interactions. It is important that pharmacy staff have up-to-date knowledge of effective pain management strategies, including non-drug options to be used either alone or as an adjunct to medication.

Prior to 1 May 2010, ensure staff members are aware of their professional responsibilities with regard to the supply of analgesics. Discourage stockpiling by patients and consider developing an in-pharmacy policy for dealing with requests for multiple packs.

Staff should also review the PSA Professional Standards (Standards for the provision of Pharmacy Medicines and Pharmacist Only Medicines in community pharmacy) available at www.psa.org.au

5. Quality Assurance
Prior to the changes coming in on 1 May 2010, pharmacies accredited under the Quality Care Pharmacy Program (QCPP) should ensure they continue to meet relevant QCPP Standards.

Pharmacy Guild Support Material
Detailed information about the changes and support tools to assist pharmacy staff in managing the change has been prepared by the Pharmacy Guild of Australia and is available online at www.guild.org.au. Readers should refer to these materials and have them available to assist staff and customers with the changes.

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