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INFORMATION CIRCULAR TO PHARMACISTS IN TASMANIA

I. Changes to the scheduling of combination analgesics containing codeine

As most pharmacists will be aware, the scheduling of combination analgesics containing codeine (CACC) will change nationally from the 1st May this year, consistent with recommendations from the National Drugs and Poisons Scheduling Committee (NDPSC) *. The schedule 2 classification for these analgesics will be deleted. The Schedule 3 amendment will then capture these products:

Schedule 3:

CODEINE when:

- (a) not combined with any other opiate substance;
- (b) compounded with one or more other therapeutically active substances, of which not more than one is an analgesic substance:
 - (i) in divided preparations containing 12 mg or less of codeine per dosage unit;
or
 - (ii) in undivided preparations containing 0.25 per cent or less of codeine; and
- (c) labelled with a recommended daily dose not exceeding 100 mg of codeine; and
- (d) in packs containing not more than 5 days of supply at the maximum dose recommended on the label,

except when included in Schedule 2 (Note: Cough and cold preparations remain in Schedule 2).

* Subject to Ministerial approval.

The details of the new scheduling for codeine (Schedules 2, 4 and 8) is also given in Appendix A.

The recommendations from the NDPSC have been driven by a wide concern at the misuse of compound analgesics containing codeine and many submissions were received from medical practitioners, pharmacists and the broader community. Similar concern has also seen regulatory moves in the United Kingdom and New Zealand to restrict access to over the counter codeine products.

There are a number of aspects to the changes:

1.1 A limit to the size of packs

As most acute conditions resolve within 3-5 days, packs sizes have been limited to 5 days supply. This is consistent with UK and NZ changes.

1.2. A limit on unit dose

The issue of unit dose was the subject of a review by a sub-committee that looked at all the relevant available scientific literature. Despite codeine having been used as a sole agent for nearly two centuries, there is no rigorous evidence around the effective doses and it has been argued that codeine doses in many current OTC preparations represent a sub-therapeutic dose. Most of the pharmacopoeias and drug literature recommend a dose of 30 to 60 mg of codeine phosphate. The NDPSC supported the availability, with pharmacist control, of a more effective dose and therefore recommended a maximum unit dose of 12 mg (equating to 15mg of codeine phosphate). It should be noted that 12mg represents the maximum limit and product manufacturers may choose to formulate using a lower amount, as is currently the case.

1.3. A limit on maximum daily dose

Consistent with the decision on maximum unit dose, the limit on daily dose has been raised from 60 to 100mg. (For instance, this will then allow for 8 paracetamol/codeine tablets daily with a unit dose of up to 12mg of codeine).

1.4. Advertising

Advertising of Schedule 3 codeine preparations is not allowed under existing provisions. Any change to this has not been supported by the committee, as no public health benefit was established for their promotion. Addiction specialists argued strongly that visual cues and sales promotions could stimulate desire in habituated individuals.

2. Codeine combinations for coughs and colds

The committee decided that the current scheduling of codeine combinations for coughs and colds remained appropriate. The committee agreed to review the misuse/abuse of the Schedule 2 products twelve months after the implementation of the combination analgesics containing codeine rescheduling decision.

3. Implementation date and an exemption for labelling under the *Poisons Regulations 2008*

There are substantial changes required by the pharmaceutical industry, and the rates that companies will be able to print new packaging and amend their production processes will vary. Also the existing and new stock of the many products will proceed through the distribution chain to pharmacies, and be supplied by pharmacies, at different rates.

Therefore an exemption is being issued by this state to companies to allow for the supply of stock that may indicate the incorrect schedule both before and after the implementation date. **Please note that the exemption relates to the labelling only and storage and supply conditions must be complied with (See item 4 below).** The exemptions are consistent with those issued by other states and territories and in summary have the following conditions:

1. Stocks of combination analgesics containing codeine which have been **manufactured and released for sale by the sponsor on or before 31 December 2009** may continue to be supplied by wholesalers and pharmacists (but not by the sponsor) after 1 May 2010, if labelled in accordance with the previous schedule (Schedule 2 or 3), despite the product being included in a different Schedule (Schedule 3 or 4).

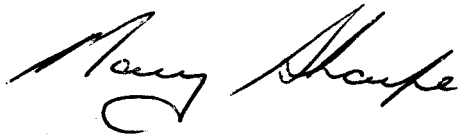
This exemption applies only until the formerly labelled stock of the product is exhausted, but no later than 31 December 2010. (e.g. a pack of 24 tablets in Schedule 2, held by a pharmacy and labelled S2 in the period before 1 May 2010, may still be issued after that date but as a Schedule 3 product)

2. Stocks of combination analgesics containing codeine which have been **manufactured and released for sale by the sponsor on or after 1 January 2010** may be supplied by the sponsor, wholesaler, or pharmacies up until 30 April 2010, if labelled in accordance with the Schedule (Schedule 3 or Schedule 4) that will apply as from 1 May 2010, despite the product being currently included in a different Schedule (Schedule 2 or Schedule 3). (e.g. a pack of 48 tablets, labelled as S4, may be forwarded to a pharmacy before 1 May 2010, but may be supplied by a pharmacist consistent with the scheduling applying at that time, that is Schedule 3. The Schedule 4 restrictions will apply after the 1 May change.)

4. Storage and supply

Please note that the exemptions only apply in respect of labelling and that otherwise scheduling changes at the applicable dates must be observed in respect of storage and supply (That is, all stock must be stored in the dispensary and be supplied by a pharmacist after 1 May 2010 and, for instance, a pack containing in excess of 5 days supply of tablets can only be supplied as an S4 after that date).

Please contact the Branch if you have any queries.



Mary Sharpe
Chief Pharmacist
23rd February 2010

Appendix A- Scheduling as of 1 May 2010

Schedule 2 entry

CODEINE in preparations for the treatment of coughs and colds when:

- (a) not combined with any other opiate substance;
- (b) compounded with one or more other therapeutically active substances, of which at least one is phenylephrine and not more than one is an analgesic substance:
 - (i) in divided preparations containing 10 mg or less of codeine per dosage unit;
or
 - (ii) in undivided preparations containing 0.25 per cent or less of codeine;
- (c) labelled with a recommended daily dose not exceeding 60 mg of codeine; and
- (d) in packs containing not more than 6 days of supply at the maximum dose recommended on the label.

Schedule 4

Codeine when compounded with one or more therapeutically active substances-

- (a) in divided preparations containing 30mg or less of codeine per dosage unit; or
- (b) in undivided preparations containing 1% or less of codeine-
except when included in Schedule 2 or 3.

Schedule 8

Codeine except when included in Schedule 2, 3 or 4