AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL

MINUTES

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

(NDPSC)

MEETING NUMBER 22

August 1999

Venue: Conference Room No 2
Ground Floor
Juliana House
Bowes Street
WODEN ACT 2606

Telephone: 02-6289 6968 **Fax:** 02-6289 7134 (Conf Room)
02-6289 7222 (3rd Floor Juliana)

Session Times:

17 August 1999	9.00am to 5.30 pm
18 August 1999	8.30 am to 5.30 pm
19 August 1999	8.30 am to 4 pm

RATIFIED
16 September 1999

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[redacted]

1.8 NDPSC WORKING PARTIES

1.8.1 TRANS-TASMAN HARMONISATION WORKING PARTY

1.8.1.1 Matters Arising from Second and Third Meetings of Working Party

[redacted]

[redacted]

Recommendation No 71/4

THE NDPSC SHOULD BE ADVISED TO ADOPT THE FOLLOWING DRUGS INTO SCHEDULE 4:

TRAZADONE
[redacted].

The Committee noted the above drugs were included in Schedule 1, Part 1 in NZ.

The Committee noted:

- Trazadone is an antidepressant with little antimuscarinic activity but marked sedative properties;
- [redacted]
- [redacted]

The Committee supported a Schedule 4 classification.

DECISION NO. 1999/22 - 86

Schedule 4 – New entries

TRAZADONE.

[redacted]

MINUTES

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

(NDPSC)

MEETING NUMBER 24
(First Meeting of the Statutory Committee – Transitional Meeting)

16 November 1999

Venue Conference Room No 2
Ground Floor
Juliana House
Bowes Street
WODEN ACT 2606

Telephone 02-6289 6968 **Fax** 02-6289 7134 (Conf Room)

Session Times 11:00 am to 12:00 noon

RATIFIED MINUTES
16 December 1999

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[redacted]

[redacted]

[redacted]

[redacted]

3.1.t4 Trazadone, [redacted] and [redacted]

The committee noted that:

> *New Schedule entries were made for the purposes of obtaining consistency between Australian and NZ Schedules, arising from Trans-Tasman Harmonisation Working Party recommendations, considered by the NDPSC at the August 1999 Meeting. DECISION NO. 1999/22-86 and AMENDMENT 2 TO SUSDP 14 refer.*

With regard to trazadone, [redacted] and [redacted], the Committee accepted the findings of AHMAC Committee in relation to matters mentioned in subsection 52E (1) of the Act, and decided that there should be no variation to the scheduling decision taken by AHMAC Committee.

The new entries made by the AHMAC Committee were:

Schedule 4 – New entries

TRAZADONE.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

National Drugs and Poisons Schedule Committee

Ratified Minutes

47th Meeting
20-22 June 2006

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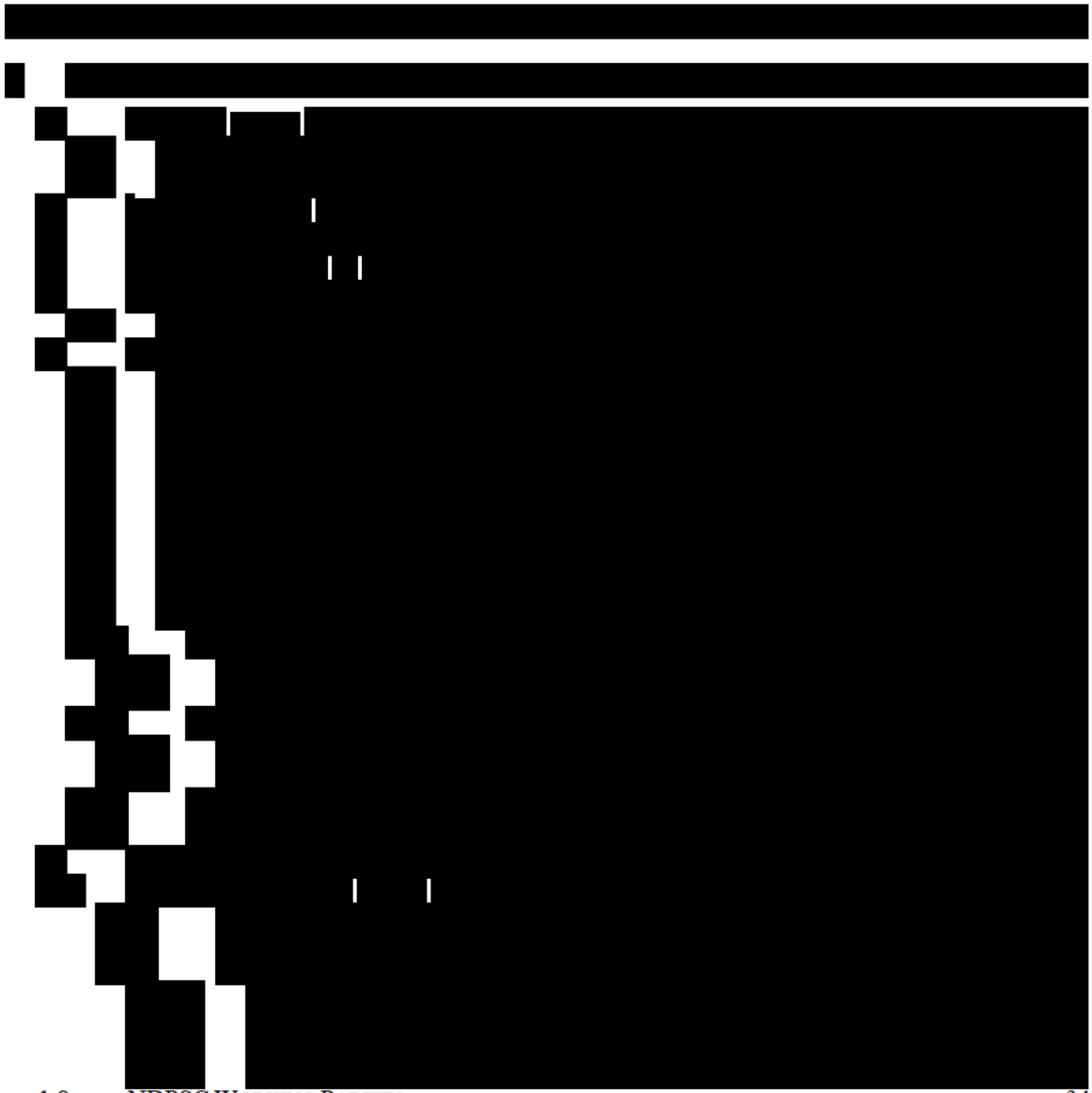

[redacted]

[redacted]

1.8.1.2 UNHARMONISED MEDICINES IN THE AUSNZ SCHEDULING DATABASE

PURPOSE

The Committee considered the recommendations of the June 2006 TTHWP meeting.

BACKGROUND

The June 2006 TTHWP meeting was advised that processing of medicine records in the AusNZ Scheduling Database for substances listed in S2, S3, S4 and S8 and equivalent New Zealand classifications including General Sale had been completed. Substances identified as unharmonised, i.e. Not Harmonised, Partially Harmonised or Essentially Harmonised which included substances requiring a minor nomenclature change, eg harmonising with New Zealand on the INN and substance parent entry, had been summarised and tabled for consideration at the June 2006 TTHWP meeting.

Working Party members considered each unharmonised substance and agreed on appropriate recommendations to be tabled at the NDPSC June 2006 meeting.

DISCUSSION

The Committee noted that the following policy approaches and principles for harmonisation of scheduling and nomenclature were taken into account by the TTHWP in formulating its recommendations:

- As set out in the *Principles of Harmonisation of Scheduling of Drugs and Poisons* established 1998, there should be equivalent scheduling for drugs and poisons for both countries; equivalent general exemptions from scheduling; a common set of definitions and scheduling criteria and guidelines; consistent interpretation of scheduling criteria; common nomenclature for drugs and poisons; harmonisation of labelling and packaging; and harmonisation of safety directions, warning statements and first aid instructions. Within the Schedules, there should be common descriptions for generic drug and poison classes (eg benzodiazepines, alkaline salts) or any other general classification (eg anabolic steroidal agents).
- [redacted]

- Harmonise with New Zealand on the nomenclature of substances, where appropriate, eg harmonising on the INN and substance parent entry;
- S2 and S3 substances where no products containing these substances are being marketed in either Australia or New Zealand should be deleted and the parent compounds be added or retained in S4 of the SUSDP.
- Where one country includes a new medicine in S4/Part I as part of a registration application, e.g. medicines recommended for approval by the ADEC, the other country should harmonise and adopt the same classification and nomenclature according to agreed policies, where appropriate.
- Where it has been identified that one country has an existing medicine entry in S4/Part I, the other country should harmonise and also adopt the same classification and nomenclature according to agreed policies, where appropriate. This approach should similarly apply to existing S4/Part I entries where no products are currently on the market in either Australia or New Zealand or where they are no longer in current use in other countries including those no longer listed in Martindale (obsolete).

The Committee noted a request from industry to consider harmonisation of the scheduling of [redacted] and [redacted] with New Zealand at the February 2007 meeting.

OUTCOME

The Committee endorsed the TTHWP recommendations and agreed that substances for consideration of the NDPSC should be included on the agenda and pre-meeting gazette notice of the October 2006 NDPSC meeting. Similarly, the Committee agreed that recommendations to New Zealand should be referred to the MCC consideration at its next meeting.

ACTION

- *Refer NDPSC harmonisation recommendations to MCC for consideration.*
- *Include in the October 2006 pre-meeting gazette notice the list of substances for consideration of harmonisation with New Zealand.*
- *Include on the agenda and pre-meeting gazette notice of the February 2007 meeting consideration of* [redacted] *and* [redacted].
- *Seek comment from DSEB re proposal to delete the exemption for* [redacted].
- *Seek comment from ODBT if the entry '* [redacted] *would not impact on medical devices and seek confirmation that* [redacted] *are exempt via Appendix A.*

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– *Advise DSEB, OTC and OCM of items for consideration at the October 2006 NDPSC meeting and invite comments.*

– *Include on the agenda of February 2007 NDPSC meeting items foreshadowed to be considered at this meeting.*

TABLE 1 –HARMONISATION RECOMMENDATIONS TO NDPSC

Substance	Australian Schedule/ New Zealand Classification		Comment	TTHWP Recommendations
	Australian	New Zealand		
PROPOSALS BASED ON LEAST RESTRICTIVE SCHEDULING AND NOMENCLATURE OR WORDING ISSUES				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	S4.

[redacted]				
Australia: Trazadone New Zealand: Trazodone	**S4**	**Prescription**	Trazodone is the INN	Australia to consider amending the entry to trazodone to harmonise with New Zealand.
[redacted]				

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

National Drugs and Poisons Schedule Committee

Ratified Minutes

48th Meeting
10-12 October 2006

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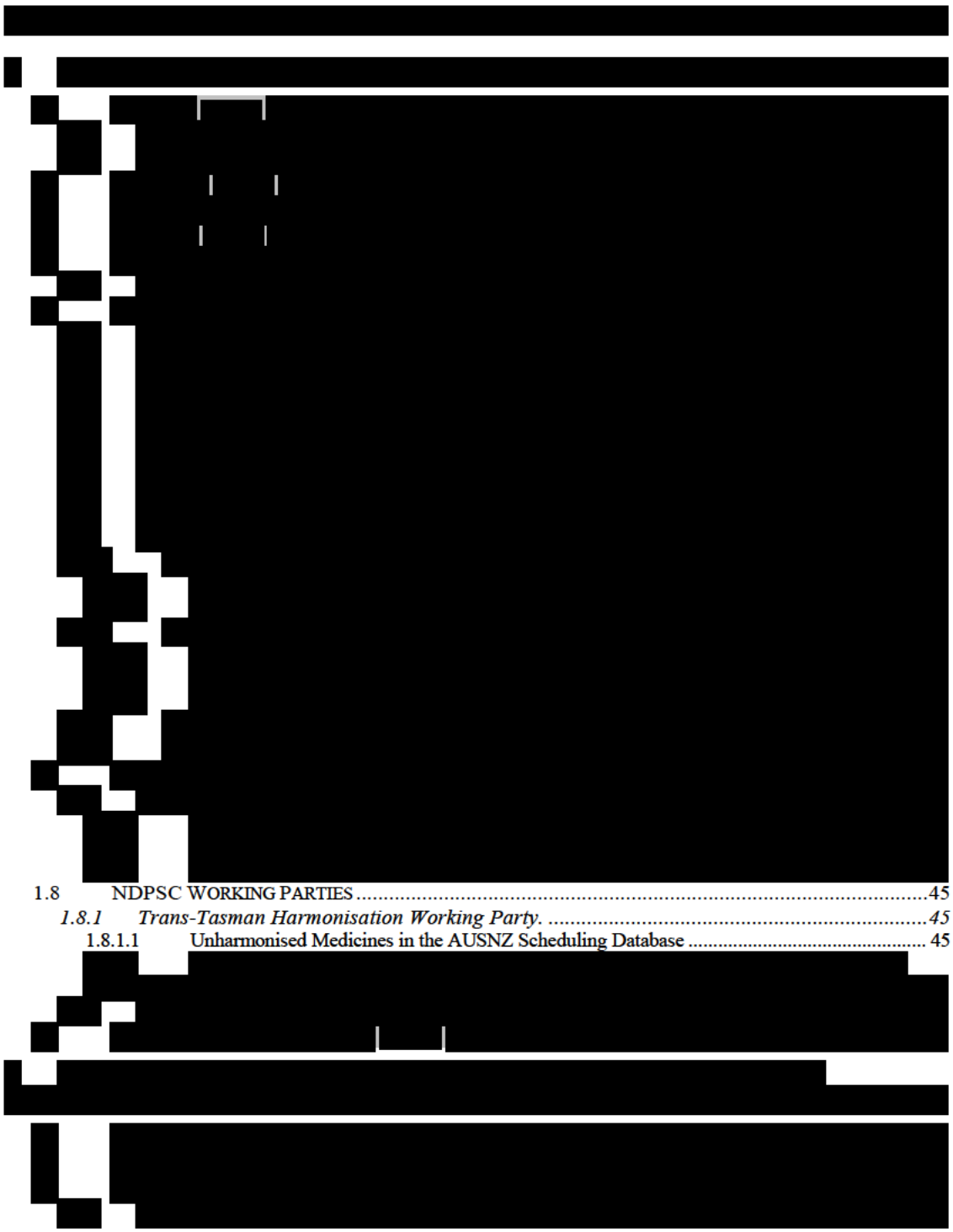


[redacted]

1.8 NDPSC WORKING PARTIES

1.8.1 TRANS-TASMAN HARMONISATION WORKING PARTY (TTHWP)

1.8.1.1 UNHARMONISED MEDICINES IN THE AUSNZ SCHEDULING DATABASE

PURPOSE

The Committee considered TTHWP recommendations for harmonisation.

BACKGROUND

The June 2006 TTHWP Meeting noted the completion of the processing of all records in the AusNZ Scheduling Database for medicines listed in Schedule 2, Schedule 3, Schedule 4 and Schedule 8 and equivalent New Zealand classifications, where available. The TTHWP considered each remaining unharmonised substance and agreed that the TTHWP's recommendations be included on the agenda of the June 2006 NDPSC Meeting.

The June 2006 NDPSC Meeting endorsed the recommendations from the June 2006 TTHWP Meeting (Table 1) and foreshadowed consideration of the remaining unharmonised medicines at the October 2006 NDPSC Meeting to allow appropriate public consultation. Similarly, the Committee agreed that the recommendations to NZ (Table 2) to harmonise the scheduling of certain medicines should be referred to the MCC for consideration. The Committee further agreed that consideration of some substances would need to be deferred (Table 3) to a future meeting to allow a more thorough risk and regulatory impact assessment and that other substances in Table 4 would remain unharmonised at this time. Members noted the request from industry to consider harmonisation of the scheduling of aspirin, paracetamol and salicylamide with New Zealand at the February 2007 NDPSC Meeting.

DISCUSSION

The Chair of the TTHWP updated the Committee on the progress of the Working Party to date. It was advised that:

- The TTHWP had agreed to recommend to the NDPSC the approach of transferring medicines currently included in Schedule 5 and Schedule 6 to the medicine Schedules while maintaining the intent to supply these medicines to the public outside the pharmacy setting provided they complied with the appropriate signal heading and precautionary warning statement requirements. To achieve this, the TTHWP proposed that primary entries for medicines currently included in non-medicine Schedules be created in the appropriate medicine Schedule and exempt these medicines from the Schedules through 'reverse scheduling' provisions. Members were advised that to expedite consideration of this matter by the NDPSC, the TTHWP agreed to seek in-principle approval from the NCCTG for this policy approach to allow consideration at the February 2007 NDPSC Meeting.
- The TTHWP advised that it planned to hold its last meeting in February 2007. At this meeting, the TTHWP would review the status of all medicines included in Table 4 (Minutes of the June 2006 NDPSC Meeting) which listed medicines which were to remain unharmonised at this time and re-confirm or amend their status as appropriate. The outcome of this meeting would be tabled at the February 2007 NDPSC Meeting.

The Committee noted and agreed to the following changes to Table 1 which was considered at the June 2006 NDPSC Meeting:

- [redacted] and [redacted] Schedule entries that were omitted from the entries in Table 1 were added and the corresponding recommendations amended accordingly.
- The recommendations to separately list [redacted] e and [redacted] were amended to cross-referencing these compounds instead to [redacted] and [redacted] respectively, as they are synonyms and as such were already appropriately scheduled and essentially harmonised with New Zealand (also listed in Appendix D).
- An alternative option was proposed for [redacted], i.e. cross-reference to [redacted], instead of including a separate entry for [redacted] in Schedule 4 as this was already covered by the Schedule 4 and Appendix K entry for [redacted] under the provisions set out in SUSDP Part 1, 1(2).

  The Committee supported this approach on the basis of simplicity and on the grounds that users were likely to refer to the index first when searching for entries in the SUSDP.
- [redacted] consideration of harmonisation was deferred pending the outcome of the review of blood products.
- [redacted] (see item 13.1.2), [redacted] (see item 12.1.4), [redacted] (see item 12.1.6) were tabled at the October 2006 NDPSC Meeting as separate items due to other considerations.
- The recommendation in relation to [redacted] and [redacted] was amended to allow separate listings for these medicines as they are different compounds although listed as synonyms in the SUSDP and Table 1.
- The recommendation and proposed entry for [redacted] was amended to remove [redacted] from the substance entry and cross-reference [redacted] to [redacted] in the index of the SUSDP.
- [redacted] and [redacted] were covered by the entry for [redacted] in Appendix C for human internal use, except when being used solely for experimental purposes in humans, and Schedule 4 for topical preparations. To reflect this, the recommendation was amended to [redacted] In addition, the Committee agreed to recommend that New Zealand delete the General Sale entry for external preparations to harmonise with the Schedule 4 status in Australia but retain the Prescription Medicine entry for [redacted] and [redacted] due to the lack of an equivalent mechanism to Appendix C in New Zealand. On this basis, the Committee agreed that [redacted] and [redacted] be also

included in the list of medicines for which harmonisation could not be achieved at this time.

The Committee was advised that following the June 2006 NDPSC Meeting the following actions were taken:

- Comment was sought from DSEB concerning the proposal to delete the exemption for [redacted] products but no comment was received at the time of the Meeting.
- Comment was sought from ODBT to ensure that the proposed entry [redacted] would not have any unintended impact on medical devices. ODBT subsequently advised that the proposed change would impact on a large number of low risk [redacted] products which were currently exempt from scheduling on the basis that they contained [redacted] derivatives which were excluded from the current Schedule entry for [redacted]. ODBT advised that [redacted] devices using [redacted] derivatives are low risk Class I or IIa medical devices according to the classification rules set out in Schedule 2 to the *Therapeutic Goods (Medical Devices) Regulation 2002* and that such devices are not covered by the Appendix A general exemption which applies only to Class III medical devices. Members were advised that in contrast to Australia, New Zealand medicine entries did not include derivatives or medical devices. On this basis, the Committee agreed to retain as is the current entry in Schedule 4 of the SUSDP for [redacted] which was already harmonised with New Zealand.
- General comments on the recommendations in Table 1 were sought from OCM and OTC. OCM indicated that it did not have any comments to put forward for consideration while no response was received from the OTC area.
- The draft Schedule entries which reflected the harmonisation recommendations in Table 1 were forwarded to the NDPSC Drafting Advisory Panel (DAP) for comment prior to the Meeting.

Members endorsed the DAP's proposed modifications to the draft entries arising from TTHWP recommendations foreshadowed at the June 2006 NDPSC Meeting to maintain consistency with other entries in the SUSDP. Furthermore, the Committee discussed the following issues in more detail:

- The proposed entry for [redacted] in Schedule 4 was not required as this class entry was already harmonised with New Zealand. [redacted] was mistakenly identified as unharmonised as the descriptor [redacted] was inadvertently omitted in the substance entry in Table 1.
- The draft Schedule 5 and Schedule 6 [redacted] entries appeared to be problematic because the existing exemption for [redacted] specified in Schedule 6 also covered preparations containing 25% or more of [redacted] which were included in Schedule 5. Furthermore, it was highlighted that the minutes of the August 1983 DPSSC Meeting noted that 5 ml [redacted] was likely to be a

lethal dose and it was marketed as [redacted] at that time. Members also noted that some therapeutic products may contain more than 25% [redacted]. The Committee agreed to defer and foreshadow consideration of this matter at the February 2007 NDPSC Meeting to allow a review of toxicological data and scheduling history of [redacted]. Members noted that the current entries for [redacted] appeared to have inadvertently omitted the inclusion of preparations containing more than 50% [redacted] in Schedule 6 of the SUSDP. Furthermore, the Committee agreed that the term "see also Schedule 4" in the draft Schedule entries for [redacted] should be replaced with a more appropriate wording for consistency with the style and format of scheduling conditions adopted in the SUSDP.

- Members noted that the proposed deletion of [redacted] from the [redacted] entry in Schedule 4 to retain only the parent compound and removal of the exemption for topical preparations was expected to have no regulatory impact on existing products as there were none listed on the Australian (ARTG) or New Zealand (SMARTI) database for medicines.

Members were also advised that the intent to consider the proposed inclusion in Schedule 4 of the animal-derived enzyme [redacted] to harmonise with New Zealand was inadvertently omitted from the pre-October 2006 NDPSC Meeting gazette notice. On this basis, the Committee agreed to consider this matter at the February 2007 NDSPC Meeting.

Members noted the following pre-meeting comments from the [redacted]

- [SA] expressed concern that harmonisation decisions given effect before the [redacted]

The Committee's attention was drawn by a member to the anomaly where an Appendix C substance, [redacted] which is also known as [redacted] was included in Schedule 4 to harmonise with the New Zealand Prescription Medicine status at the February 2006 NDPSC Meeting. The Committee agreed to delete the Schedule 4 entry for [redacted] which was included in SUSDP 21 Amendment 1 and to include this substance in the list of medicines for which harmonisation could not be achieved at this time. New Zealand was to be advised of this outcome.

DECISION 2006/48 - 1

On the grounds of harmonisation, the Committee agreed to amend the SUSDP based on the recommendations in Table 1 which was endorsed at the June 2006 NDPSC Meeting with minor amendments to reflect the outcome of matters discussed and agreed to at this Meeting.

[redacted]

[redacted]

TRAZADONE – amend entry to read:

TRAZODONE.

[redacted]

1.8.1.2 UNHARMONISED MEDICINES IN THE AUSNZ SCHEDULING DATABASE

PURPOSE

1. The Committee considered the recommendations of the June 2006 TTHWP meeting.

BACKGROUND

2. The Secretariat advised that processing of medicine records for substances listed in S2, S3, S4 and S8 and equivalent New Zealand classifications including General Sale classification had been completed. Substances identified as Not Harmonised, Partially Harmonised or Essentially Harmonised (which required minor change to the nomenclature, i.e. to INN) had been pre-sorted according to substances with potentially less complex harmonisation issues and substances with potentially more complex harmonisation issues.

3. The June 2006 TTHWP considered each substance listed in the table and made recommendations to harmonise the substances for endorsement by the NDPSC at its June 2006 meeting.

DISCUSSION

4. The June 2006 TTHWP meeting has recommended that unharmonised substances listed in Table 1 and 2 be considered for scheduling harmonisation, where appropriate, at the October 2006 NDPSC meeting.

5. First paragraph

OUTCOME

6.

ACTION

Action 1

[redacted]				
[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]		
[redacted]				
Australia: Trazadone New Zealand: Trazodone	**S4**	**Prescription**	Trazodone is the INN	Au ha Ze
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]				

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE
MEETING 48 – OCTOBER 2006

Agenda Item: 1.8.1.1
Originator: TTHWP
File no: refer BMC file list.

UNHARMONISED MEDICINES ON THE AUSNZ SCHEDULING DATABASE

Gazette Notice: PROPOSALS ARISING FROM TRANS-TASMAN WORKING PARTY ON THE HARMONISATION OF THE SCHEDULING OF DRUGS AND POISONS. Substances to be considered for harmonisation with New Zealand are outlined in Attachment A. Please refer to Tables 1 and 2 in the June 2006 Record of the Reasons (Agenda Item 1.8.1.2) for further information and the proposed amendments to the SUSDP.

PURPOSE

1. For the Committee to consider TTHWP recommendations for harmonisation.

BACKGROUND

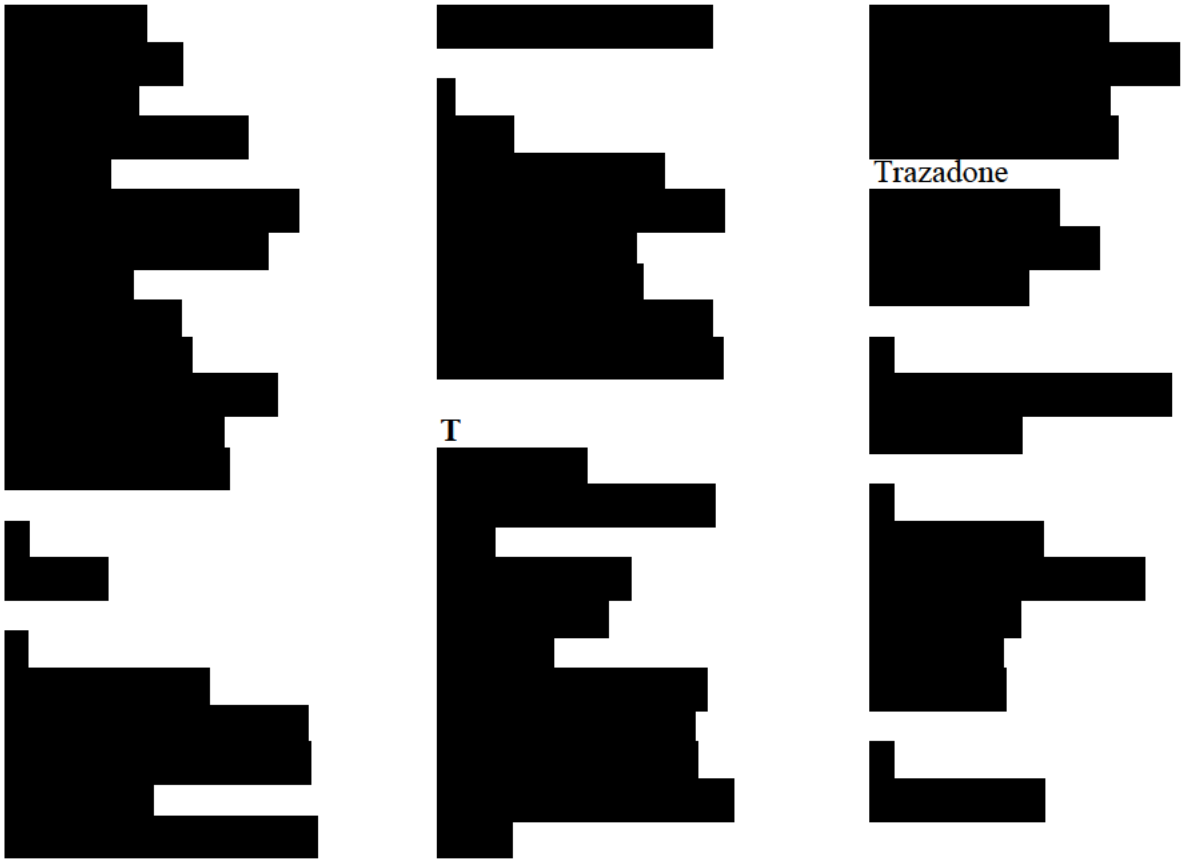
2. The June 2006 TTHWP Meeting noted the completion of processing medicine records in the AusNZ Scheduling Database for substances listed in Schedules 2, 3, 4 and 8 and equivalent NZ classifications. The TTHWP considered each unharmonised substance and agreed on recommendations (fol 14-118) to the June 2006 NDPSC Meeting.

3. The June 2006 NDPSC Meeting endorsed the TTHWP recommendations (fol 14-118) and agreed to foreshadow consideration of those pertaining to harmonisation through changes to the SUSDP (Table 1, fol 14-51) at the October 2006 NDPSC Meeting. Similarly, the Committee agreed that the recommendations to NZ (Table 2, fol 52-96) should be referred to the MCC for consideration. The Committee also agreed that consideration of some substances would need to be deferred (Table 3, fol 96-114), while other substances would remain unharmonised at this time (Table 4, fol 115-118). The Committee also noted a request from industry to consider harmonisation of the scheduling of [redacted] and [redacted] with NZ at the February 2007 meeting.

CONSIDERATIONS

4. Members are advised that there have been some changes, highlighted in blue, to the harmonisation proposals set out in Table 1 (fol 14-51), including:

- [redacted] – Schedule conditions were not fully identified.
- [redacted] – An alternative to the TTHWP recommendation has been suggested.


Trazadone
T

[redacted]

TRAZADONE – amend entry to read:

TRAZODONE.

[redacted]

TABLE 1 –HARMONISATION RECOMMENDATIONS TO NDPSC

Substance	Australian Schedule/ New Zealand Classification		Comment	TTHWP Recommendations
	Australian	New Zealand		
PROPOSALS BASED ON LEAST RESTRICTIVE SCHEDULING AND NOMENCLATURE OR WORDING ISSUES				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]
Australia: Trazadone New Zealand: Trazodone	**S4**	**Prescription**	Trazodone is the INN	Australia to consider amending the entry to trazodone to harmonise with New Zealand.
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]