



TGA THERAPEUTIC
GOODS
ADMINISTRATION

National Drugs and Poisons Schedule Committee

Record of the Reasons

35th Meeting
18-20 June 2002

The *Record of the Reasons* contains the basis of scheduling decisions and other outcomes arising from the meeting. Please note that the Secretariat is moving towards including the edited ratified minutes as the *Record of the Reasons*. With this document, we have included extracts relating to scheduling considerations of OTC medicines. The Secretariat is hopeful of including the edited ratified minutes for all areas following consultation with the respective industry bodies.

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GLOSSARY

<i>ABBREVIATION</i>	<i>NAME</i>
AAN	Australian Approved Name
ACSPA	Australian Chemicals Speciality Products Association
ADEC	Australian Drug Evaluation Committee
ADI	Acceptable Daily Intake
ADRAC	Adverse Drug Reactions Advisory Committee
AGRD	Australian Guidelines for the Registration of Drugs
AHMAC	Australian Health Ministers' Advisory Council
ANZFA	Australia New Zealand Food Authority
APAC	Australian Pharmaceutical Advisory Council
APMA	Australian Pharmaceutical Manufacturers Association
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
ARTG	Australian Register of Therapeutic Goods
ASCC	Australian Society of Cosmetic Chemists
ASCEPT	Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
BAN	British Approved Name
CAS	Chemical Abstract Service
CHC	Complementary Healthcare Council of Australia
CMEC	Complementary Medicine Evaluation Committee
CMI	Consumer Medicine Information

CNPMB	Chemicals and Non-Prescription Medicines Branch
COAG	Councils of Australian Governments
CPAS	Chemical Product Assessment Section
CPI	Consumer Product Information
CRC	Child-Resistant Closure
CRIH	Chemical Review and International Harmonization
CTFAA	Cosmetic, Toiletry & Fragrance Association of Australia
DAP	Drafting Advisory Panel
DSEB	Drug Safety and Evaluation Branch
EAGAR	Expert Advisory Group on Antimicrobial Resistance
EC	European Community
ECG	Electrocardiogram
ECRP	Existing Chemicals Review Program
EPA	Environment Protection Authority
ERMA	Environmental Risk Management Authority
FAISD	First Aid Instructions and Safety Directions
FDA	Food and Drug Administration (US)
FOI	Freedom of Information
GIT	Gastro-intestinal tract
GP	General Practitioner
GST	Goods and Services Tax
HCN	Health Communication Network

INN	International Non-proprietary Name
ISO	International Standards Organization
JETACAR	Joint Expert Advisory Committee on Antibiotic Resistance
LC ₅₀	The concentration of a substance that produces death in 50% of a population of experimental organisms. Usually expressed as mg per litre (mg/L) as a concentration in air.
LD ₅₀	The concentration of a substance that produces death in 50% of a population of experimental organisms. Usually expressed as milligrams per kilogram (mg/kg) of body weight
MCC	Medicines Classification Committee
MEC	Medicines Evaluation Committee
MOH	Ministry of Health (NZ)
NCCTG	National Coordinating Committee of Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification & Assessment Scheme
NOEL	No Observable Effect Level
NOHSC	National Occupational Health & Safety Commission
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
NZ	New Zealand
OOS	Out of Session
OTC	Over the Counter
PAR	Prescription Animal Remedy
PBAC	Pharmaceutical Benefits Advisory Committee

PEC	Priority Existing Chemical
PGA	Pharmaceutical Guild of Australia
PHARM	Pharmaceutical Health and Rational Use of Medicines
PI	Product Information
PIC	Poisons Information Centre
PMAA	Proprietary Medicines Association of Australia
PSA	Pharmaceutical Society of Australia
RFI	Restricted Flow Insert
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SVT	First aid for the solvent prevails
TCM	Traditional Chinese Medicine
TGA	Therapeutic Goods Administration
TGAC	Technical Grade Active Constituent
TGC	Therapeutic Goods Committee
TGO	Therapeutic Goods Order
TOR	Terms of Reference
TSB	Toxic Substances Board
TTHWP	Trans-Tasman Harmonization Working Party
TTMRA	Trans-Tasman Mutual Recognition Agreement
UK	United Kingdom
USA	United States of America
WHO	World Health Organization
WP	Working Party

WS

Warning statement

**2. PROPOSED CHANGES/ADDITIONS TO PARTS 1 TO 3 AND
PART 5 OF THE STANDARD FOR THE UNIFORM
SCHEDULING OF DRUGS AND POISONS.**

2.4 SUSDP, PART 5

2.4.1 PESTICIDES IN PAINT

OUTCOME

The Committee agreed to foreshadow the change to Appendix I and to seek further comment from the paint industry.

FORESHADOWED

Appendix I – Amendment

Amend paragraph 5 to read:

5. A person must not manufacture, sell, supply, or use a paint containing a pesticide **except** a fungicide, bactericide or antifouling agent.

2.4.3 APPENDIX E PART1 – STATEMENT A – NZ PIC NO.

OUTCOME

The Committee agreed to foreshadow the changes to clarify the alternatives available for the PIC number.

FORESHADOWED

Appendix E, Introduction – Amendment

Amend by adding immediately after the heading “**Poisons Information Centre Telephone Numbers**”:

Companies should use the poisons information centre telephone number(s) appropriate to the country(ies) of sale for the product, that is Australia or New Zealand or both. These are 13 1126 for Australia and 03 4747 000 for New Zealand. A new free-call number (0800 764 766) is being introduced in New Zealand. Use of the old number (03 4747 000) shall be phased out by XX May 2005.

Appendix E, Part 1 – Amendment

Statement “A” – amend statement to read:

- A For advice, contact a Poisons Information Centre (Phone *eg Australia 131 126; New Zealand 03 4747 000 [Not after XX May 2005] or 0800 764 766*) or a doctor (at once).

2.4.4 APPENDIX E PART 2 - PHENOLS

OUTCOME

The Committee agreed that statement S4 should be included in the FAIs for more concentrated phenols but that further consultation with relevant professionals and industry should occur before proceeding to implement.

FORESHADOWED

Appendix E Part 2 – Amendment

Phenols – amend entry to read:

Phenols		a,c,j,s
•	25 per cent and less	A,G3,E2,S3
•	above 25 per cent	A,G3,E2,S4

AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

4. OTHER OUTSTANDING MATTERS FROM PREVIOUS MEETINGS

4.1 DIMETHYL SULFATE

DECISION 2002/35 - 1.

The Committee agreed to recognise the upper limits for impurities contained in the *Minimum Composition Standards (MCS) for Technical Grade Active Constituents*, published by the NRA, for the purposes of exempting such impurities from the requirements of Scheduling.

Part 1 – New entry

Part 1 Interpretation, Paragraph 2 – new entry:

- (j) any substance present as an impurity in a pesticide, at a concentration at or below the maximum content for that substance, specified for the pesticide in the current version of the *Minimum Compositional Standards (MCS) for Technical Grade Active Constituents* or its successor, as published by the National Registration Authority for Agricultural and Veterinary Chemicals.

4.2 SULFOTEP

OUTCOME

Refer to Item 4.1 Methyl Sulfate for decision.

5. PROPOSED CHANGES/ADDITIONS TO THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS.

5.1 SUSDP, PART 4

5.1.1 ARSENIC

DECISION 2002/35 - 2.

The Committee agreed to rewording the entry for arsenic to conform to current editorial standards. The change was not expected to have any regulatory impact.

Schedule 6 - Amendment

ARSENIC – amend entry to read:

ARSENIC:

- (a) in ant poisons containing 0.4 per cent or less of arsenic;
- (b) in animal feed premixes containing 4 per cent or less of arsenic; or
- (c) in preparations for the treatment of animals **except** thiacetarsamide when included in Schedule 4;

except where separately specified in this Schedule.

5.1.2 CHLORINATING COMPOUNDS

OUTCOME

The Committee agreed to a final round of Industry consultation and to finalise consideration at the October 2002 meeting.

5.1.3 COPPER COMPOUNDS

DECISION 2002/35 - 3.

The Committee agreed that the known relationship of toxicity to availability of the copper ion in combination with the low risks associated with the use of pigments, warranted the exemption from scheduling of copper pigments whose solubility in water was less than or equal to 1 g/L.

The Committee agreed to also to clarify the exemptions from Schedule 6 to include the exemption for feed additives containing 1 per cent or less of copper.

Schedule 6 - Amendment

COPPER COMPOUNDS – amend entry to read:

COPPER COMPOUNDS **except**:

- (a) when separately specified in these Schedules;
- (b) in preparations for human internal use containing 5mg or less of copper per recommended daily dose;
- (c) pigments where the solubility of the copper compound(s) in water is 1 gram per litre or less;
- (d) in feed additives containing 1 per cent or less of copper; or

- (e) in other preparations containing 5 per cent or less of copper compounds.

5.1.4 ORGANOTIN COMPOUNDS

OUTCOME

The Committee did not agree to reschedule the organotin compounds or dibutyltin dilaurate (DBTL) and confirmed that paint additives containing organotin compounds were appropriately included in Schedule 7. Further consideration would require formulation, packaging and use data for the individual products, final end use concentrations, along with a full package of toxicity data addressing in particular, concerns about the teratogenicity of DBTL.

5.1.5 ACRYLAMIDE

OUTCOME

The Committee considered the NICNAS Prior Existing Chemical Report on acrylamide and noted the conclusion that there were negligible public health risks associated with ingestion of acrylamide in water and food or from dermal absorption from cosmetic products. Accordingly, the Committee agreed there were no grounds for Scheduling acrylamide to control the level of this impurity in consumer products.

5.1.6 HYDROFLUORIC ACID

OUTCOME

The Committee agreed that products containing hydrofluoric acid in the range 1-10% were appropriately included in Schedule 7 on the basis of their toxicity. Members reaffirmed that only Schedule 7 provided adequate control mechanisms for HF with exclusion from the domestic market in the majority of States and Territories. The Committee noted that there was already suitable exemption for industrial products from the labelling and packaging requirements of the SUSDP through paragraphs 13 and 26 of Part 2 – Labels and Containers. The Committee further recommended that individual jurisdictions examine the impost of licensing controls on HF products for industrial use.

5.1.7 LITHIUM IN PIGMENTS

OUTCOME

The Committee agreed to consult with industry on the following proposals for lithium prior to consideration at the October 2002 meeting.

FORESHADOWED

Schedule 4 - Amendment

LITHIUM – amend entry to read:

LITHIUM (excluding when present as an excipient at x per cent or less of lithium) for therapeutic use, **except:**

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.01 per cent or less of lithium.

Schedule 2

LITHIUM (excluding when present as an excipient at x per cent or less of lithium) for therapeutic dermal use in preparations containing 1 per cent or less of lithium **except** in preparations containing 0.01 per cent or less of lithium.

5.1.8 LIMONENE

OUTCOME

The Committee noted the NICNAS Priority Existing Chemical Report on limonene and considered that the toxicity profile was consistent with exemption from the requirements of the SUSDP.

**6. MATTERS REFERRED BY THE NATIONAL REGISTRATION
AUTHORITY FOR AGRICULTURAL AND VETERINARY
CHEMICALS**

6.1 ACETAMIPRID

DECISION 2002/35 - 4.

The Committee agreed that the toxicity profile of acetamiprid was consistent with inclusion in Schedule 6.

Schedule 6 - New entry

ACETAMIPRID.

6.2 IODOCARB

DECISION 2002/35 - 5.

The Committee agreed that the toxicity profile of iodocarb warranted inclusion in Schedule 6 with a cut-off to Schedule 5 for preparations containing 10% or less and exemption for aqueous preparations containing 10% or less.

Schedule 6 - New entry

3-iodo-2-propynyl butyl carbamate (Iodocarb) **except:**

- (a) when included in Schedule 5; or
- (b) in aqueous preparations containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate.

Schedule 5 – Amendment

3-iodo-2-propynyl butyl carbamate – amend entry to read:

3-iodo-2-propynyl butyl carbamate (Iodocarb) when in preparations containing 10 % or less of 3-iodo-2-propynyl butyl carbamate **except** when in aqueous preparations.

6.3 BETACYFLUTHRIN

DECISION 2002/35 - 6.

The Committee agreed that the toxicity profile for the product (an aqueous preparation) was consistent with inclusion in Schedule 5.

Schedule 5 – New entry

BETACYFLUTHRIN in aqueous preparations containing 2.5 per cent or less of betacyfluthrin.

Schedule 6 – Amendment

BETACYFLUTHRIN – amend entry to read:

BETACYFLUTHRIN in preparations containing 12.5 per cent or less of betacyfluthrin **except** when included in Schedule 5.

Schedule 7 – Amendment

BETACYFLUTHRIN – amend entry to read:

BETACYFLUTHRIN **except** when included in Schedule 5 or 6.

6.4 INSULIN-LIKE GROWTH FACTOR I

OUTCOME

The Committee agreed that the potential for abuse and diversion warranted inclusion of a generic entry for the insulin-like growth factors in Schedule 4 and an entry under Paragraph 5 of Appendix D to control illegal possession. Members agreed that these proposals be foreshadowed to allow for public consultation.

FORESHADOWED

Schedule 4 – New entry

#INSULIN-LIKE GROWTH FACTORS **except** when separately specified in this Schedule.

Appendix D, Paragraph 5 – New entry

INSULIN-LIKE GROWTH FACTORS.

Index – New entry

SOMATOMEDINS *see* INSULIN-LIKE GROWTH FACTORS

DECISION 2002/35 - 7.

The Committee agreed that the veterinary use of IGF-I required professional diagnosis and management of use warranting inclusion of IGF-I in Schedule 4. In addition the Committee noted that inclusion in Schedule 4 would also provide a barrier to diversion during manufacture through licensing requirements.

Schedule 4 - New entry

INSULIN-LIKE GROWTH FACTOR I.

6.5 PRALLETHRIN

DECISION 2002/35 - 8.

The Committee agreed that the toxicity profile for formulations containing 10% or less of prallethrin was consistent with inclusion in Schedule 5. Further, an exemption for insecticidal mats containing 1% or less of prallethrin was considered to be consistent with the existing allethrin exemption for insecticidal mats, as it allows for the 10-fold greater inhalational toxicity of prallethrin.

Schedule 6 – Amendment

PRALLETHRIN – amend entry to read:

PRALLETHRIN (cis:trans=20:80) **except**:

- (a) when included in Schedule 5; or
- (b) in insecticidal mats containing 1 per cent or less of prallethrin.

Schedule 5 – New entry

PRALLETHRIN (cis:trans=20:80) in preparations containing 10 per cent or less of prallethrin **except** in insecticidal mats containing 1 per cent or less of prallethrin.

6.6 RACTOPAMINE

DECISION 2002/35 - 9.

The Committee agreed that the need for professional management and intervention for therapeutic uses and the need to control potential diversion and abuse, warranted inclusion of ractopamine in Schedule 4. The Committee further agreed that the toxicity profile of ractopamine, when formulated as an animal feed premix was consistent with inclusion in Schedule 5.

Schedule 4 - New entry

RACTOPAMINE **except** when included in Schedule 5.

Schedule 5 – New entry

RACTOPAMINE in animal feed premixes containing 10 per cent or less of ractopamine.

6.7 BENTONITE

DECISION 2002/35 - 10.

The Committee agreed that the toxicity profile and existing experience with the use of bentonite in therapeutic and cosmetic preparations supported the exemption of bentonite from the requirements of the SUSDP for all uses.

**8. ANTIBIOTICS FOR CONSIDERATION FOLLOWING
RECOMMENDATIONS OF THE JOINT EXPERT TECHNICAL
ADVISORY COMMITTEE ON ANTIBIOTIC RESISTANCE
(JETACAR)**

8.1 IONOPHORES - JETACAR

OUTCOME

The Committee received submissions and an assessment from EAGAR on the polyether ionophores, and agrees that there is no need to alter the current scheduling of the polyether ionophores on the basis of antibiotic resistance.

8.2 VIRGINIAMYCIN

This item was deferred to the October 2002 meeting pending receipt of the final report from the NRA.

8.3 JETACAR FUTURE REVIEWS

OUTCOME

The Committee confirmed that the review of intramammary antibiotics would proceed at the October 2002 meeting.

9. OTHER MATTERS FOR CONSIDERATION

9.1 GLYCOLIC ACID

OUTCOME

The Committee agreed that the available information did not warrant scheduling action and referred the incident report to the relevant jurisdiction.

10. INITIAL REVIEW AND/OR FORMAL OPINIONS

10.1 CREOSOTE

ERRATA 2002/35 - 11.

The Committee agreed that the Schedule 6 entry for creosote be amended to ensure that those preparations exempted from Schedule 2 were also exempted from Schedule 6.

Schedule 6 - Amendment

CREOSOTE – amend entry to read:

CREOSOTE except:

- (a) when included in Schedule 2;
- (b) in preparations for human therapeutic use containing 10 per cent or less of creosote; or
- (c) in other preparations containing 3 per cent or less of phenols and homologues of phenol boiling below 220°C.

PHARMACEUTICALS

12. OTHER OUTSTANDING MATTERS FROM PREVIOUS MEETINGS

12.1 MELIA AZEDARACH

OUTCOME

The Committee agreed to foreshadow inclusion in Appendix C of *Melia azedarach* or its extracts or its derivatives, on public health and safety grounds.

FORESHADOWED

Appendix C - New entry

MELIA AZEDARACH (chinaberry) or its extracts or its derivatives.

12.2 AZADIRACHTA INDICA (NEEM)

OUTCOME

The Committee annulled the February 2002 decision **2002/34 – 6** (as follows).

Schedule 7 - New entry

AZADIRACHTA INDICA (Neem) or its extracts or its derivatives, in preparations for:

- (a) agricultural use **except** when included in Schedule 5; or
- (b) veterinary use.

Schedule 5 – New entry

AZADIRACHTA INDICA (Neem) (extracted from seed kernels using water, methanol or ethanol) in preparations for agricultural use containing 5% or less of total limonoids.

FORESHADOWED

Appendix C – New entry

AZADIRACHTA INDICA (Neem) or its extracts or its derivatives, in preparations for human use.

*****End of Decision 2002/34 - 6

FUTURE ACTION

The Committee determined that any further consideration of the scheduling of Neem be deferred to the next meeting on 15-17 October 2002.

12.3 SIBUTRAMINE

OUTCOME

The Committee agreed to not proceed with the foreshadowed decision to include sibutramine in Appendix K of the SUSDP, on the basis of expert advice and data from clinical studies indicating that there was no significant difference in incidence rates for drowsiness between sibutramine and placebo.

However, the Committee agreed to foreshadow the inclusion of fluvoxamine and venlafaxine in Appendix K of the SUSDP, as the available information indicated significantly higher incidence rates for drowsiness compared with placebo.

FORESHADOWED

Appendix K - New entries

Fluvoxamine

Venlafaxine

DECISION 2002/35 - 12.

The Committee agreed to implement the foreshadowed decision to include ziprasidone in Appendix K of the SUSDP, based on expert advice and information specified in the Product Information indicating that clinical trials with ziprasidone showed a significantly higher potential to cause drowsiness compared with placebo.

Appendix K - New entry

Ziprasidone

12.4 ZIPRASIDONE

Discussed under Item 12.3 - Sibutramine.

12.5 IPRIFLAVONE

PURPOSE

The Committee considered the foreshadowed inclusion of ipriflavone in Schedule 4.

BACKGROUND

Ipriflavone is a synthetic iso-flavone which had been widely promoted for muscle building, weight management and treatment for a range of female conditions including osteoporosis. Evidence had suggested that ipriflavone itself is devoid of oestrogen-like activity although one of its flavonoid component, daidzen (also found in soy), had been found to be hormonally active.

The Complementary Medicines Evaluation Committee (CMEC) had rejected an application by XXXXXXXXXXXX to include ipriflavone as a listable ingredient. CMEC's decision was based on the grounds that ipriflavone did not fall within the scope or intent of Schedule 14 of the Therapeutic Goods Regulations, which defined designated active ingredients. In addition, CMEC had stated that there were no traditional uses identified for ipriflavone and it was not considered a precursor for a substance with uses in traditional medicine. CMEC subsequently referred ipriflavone to the November 2001 MEC meeting for consideration, but MEC again rejected ipriflavone as an ingredient for listed or registered medicines on the grounds that there was insufficient safety data. Following this meeting, the matter was referred to NDPSC by the MEC Secretariat for consideration of scheduling.

The February 2002 NDPSC meeting noted that the OTC Evaluation report supported the findings published in the Journal of the American Medical Association (JAMA, 2001;285:1482-1488), stating there were no significant differences between the study group and placebo for any of the clinical parameters studied as markers of osteoporosis. The Committee also noted that the OTC evaluation report had stated that there was a statistically significant increase in the incidence of lymphocytopenia in the study group compared to placebo (12.4% vs. 0.4%). The OCM evaluation report had stated that a range of adverse reactions associated with ipriflavone included GIT symptoms and liver enzyme changes. Furthermore, a concern was raised at the February 2002 NDPSC meeting, regarding products containing an unregistered substance and being sold in Australia as a body building aid, which is an unapproved therapeutic indication. Subsequently, this meeting agreed to foreshadow the inclusion of ipriflavone in Schedule 4, on the grounds that the safety and efficacy of ipriflavone required further evaluation, and the proposed indication for use in the treatment of osteoporosis required medical diagnosis and management.

No products containing ipriflavone were listed on the ARTG.

DISCUSSION

The Committee noted the pre-meeting comment received from XXXXXXXXXXXXXXXX indicating that it had no firm position as yet with regard to the appropriateness of including ipriflavone in Schedule 4. Also noted was XXXXXXXXXXXXXXXX advice that ipriflavone was being marketed in the US as a non-prescription dietary supplement and inclusion in S4 may present a TTH issue, as ipriflavone was potentially available in food-based products under the NZ Dietary Supplements Regulations. Additionally, the Committee was informed that OCM was not intending on making a formal submission on the scheduling of ipriflavone.

Members again raised the issue of uncontrolled availability of unregistered therapeutic goods to the public, particularly when such products had been associated with adverse effects and the indications advertised on the Internet, i.e. for muscle building, was likely to increase the potential for abuse.

The Committee noted that there was insufficient evidence available to demonstrate the safety and efficacy of ipriflavone and had remained concerned over the potential long-term effects. In addition, it was stated that the reported adverse effects which included GIT symptoms, liver enzyme changes and the statistically significant increase in the incidence of lymphocytopenia in study groups, needed further investigation to fully characterise the toxicity and risk profile of ipriflavone.

DECISION 2002/35 - 13.

The Committee agreed to implement the foreshadowed decision to include ipriflavone in Schedule 4 of the SUSDP, on the basis that the advertised indications, eg. treatment of a range of female conditions including osteoporosis, requires diagnosis and treatment by a medical professional. In addition, the Committee was of the view that listing ipriflavone in S4 would place appropriate control on access to this potentially toxic substance and ensure that personally imported products containing ipriflavone would not be available unless a qualified medical practitioner has issued a prescription for that individual. Placing ipriflavone in Schedule 4 would also require that any application to market a product based on ipriflavone would undergo a full safety assessment by the Drug Safety Evaluation Branch of the TGA.

Schedule 4 - New entry

IPRIFLAVONE.

12.7 CLOBETASONE

PURPOSE

The Committee considered post-meeting comments from XXXXXXXXXXXXXXXX seeking reconsideration of the February 2002 Meeting decision relating to the proposal to include clobetasone in Appendix H of the SUSDP.

BACKGROUND

Clobetasone-17-butyrate eumovate, a corticosteroid with glucocorticoid activity, was first included in S4 of the SUSDP in March 1980, with no cut-offs to less restrictive Schedules. XXXXXXXXXXXXXXXX had planned to market a product in Australia, XXXXXXXXXXXXXXXX Cream, containing 0.05% clobetasone butyrate in a pack size of XXXXXXXXXXXXXXXX. The proposed indication was for short-term treatment (7 days) and control of patches of eczema and dermatitis, including atopic and seborrhoeic eczema, and primary irritant and allergic dermatitis on certain areas of the body for use in adults and children over 12 years of age.

The February 2002 NDPSC Meeting considered an application from XXXXXXXXXXXXXXXX seeking to have dermal preparations containing 0.05% or less of clobetasone in packs containing 30 g or less rescheduled from S4 to S3. Additionally, XXXXXXXXXXXXXXXX sought inclusion of clobetasone in Appendix H of the SUSDP (Schedule 3 poisons permitted to be advertised).

The Committee agreed to include clobetasone in Schedule 3, when in preparations for dermal use containing 0.05% or less of clobetasone in packs containing 30 g or less, for use in adults and children 12 years and over. This decision was based on the safety and well-characterised side effect profile of 0.05% clobetasone, which was considered comparable to 1% hydrocortisone cream. In contrast, the proposal to include clobetasone, a moderately potent corticosteroid, in Appendix H (poisons permitted to be advertised) was not supported due to the absence of appropriate post-marketing experience in Australia.

No products containing clobetasone were listed on the ARTG or PUBCRIS at the time of the meeting. The Medsafe database listed dermal preparations (cream and ointment) containing 0.05% clobetasone in 30 g and 100 g tubes.

DISCUSSION

The Committee noted the February 2002 post-meeting comment from XXXXXXXXXXXXXXXX seeking reconsideration of the decision not to include clobetasone in Appendix H of the SUSDP. XXXXXXXXXXXXXXXX had raised the following points in support of inclusion:

- The potential benefit of increased public knowledge on early detection and treatment of skin conditions including eczema and contact dermatitis would reduce the burden on the public health system as a result of fewer visits to the General Practitioner.
- XXXXXXXXXXXXXXXX had the same indication as 0.5% hydrocortisone cream for dermal use (S2), which made XXXXXXXXXXXXXXXX appropriate for advertising. In addition, advertising of 0.05% clobetasone was not likely to discourage pharmacists from recommending less efficacious products, if a patient only suffered from a milder form of eczema.

- Advertising of XXXXXXXXXXXXXXX in XXXXXXXXXXXXXXX since 2001 had shown that such activity had not been associated with consumer harm and the product would unlikely be the subject of inappropriate use or abuse. In addition, XXXXXXXXXXXXXXX had intended to submit to the TGA identical labelling and package leaflet used in the XXXXXXXXXXXXXXX and conduct a local readability study to confirm the XXXXXXXXXXXXXXX findings that consumers had understood how to use the product correctly.
- XXXXXXXXXXXXXXX was registered and marketed in Australia from 1982-1989 by XXXXXXXXXXXXXXX, during which no adverse reports were recorded in the ADRAC database. Furthermore, the product had 20 years history of safe use worldwide to reinforce the local Australian experience of 6-7 years.
- XXXXXXXXXXXXXXX was of the view that quality use of XXXXXXXXXXXXXXX could be achieved through a combination of responsible advertising and counselling by a pharmacist. It was indicated that any advertising done by XXXXXXXXXXXXXXX directed sufferers to not self-treat but encouraged patients to discuss the symptoms with the pharmacist in order to obtain appropriate advice.
- Statistical evidence clearly showed that even though products had been available as S3 medication, Australians might still visit their doctors for treatment of an already diagnosed condition due to the lack of knowledge on the availability of efficacious and safe products which could be obtained from the pharmacist.

Members were of the view that XXXXXXXXXXXXXXX had provided sufficient information to address the Committee's initial concerns and proposed that clobetasone be included in Appendix H of the SUSDP.

OUTCOME

Based on available information, the Committee agreed to vary the amendment relating to clobetasone made at the February 2002 meeting to include clobetasone in Appendix H of the SUSDP on the grounds of potential public health benefits.

Variation to DECISION 2002/34 - 17.

Schedule 3 – New entry

CLOBETASONE (clobetasone-17-butyrate) in preparations for dermal use containing 0.05 per cent or less of clobetasone in packs containing 30 g or less of such preparations.

Schedule 4 – Amendment

CLOBETASONE – amend entry to read:

CLOBETASONE (clobetasone-17-butyrate) **except** when included in Schedule 3.

Appendix F, Part 1 – New entry

95. CAUTION - Do not use for children under 12 years old unless a doctor has told you to.

Appendix F, Part 3 – New entry

Clobetasone when included in Schedule 3.....95,72,73,74,75

Appendix H - New entry

Clobetasone.

13. PROPOSED CHANGES/ADDITIONS TO THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS.

13.1 SUSDP, PART 4

13.1.1 POLYSULPHATED GLYCOSAMINOGLYCANS

OUTCOME

The Committee agreed to the proposed editorial amendment for consistency of wording.

Schedule 4 – Editorial amendment

POLYSULPHATED GLYCOAMINOGLYCANS – Correct entry to read:

POLYSULPHATED GLYCOAMINOGLYCANS in preparations for injection, **except** when separately specified in these Schedules.

13.1.2 NOMENCLATURE FOR POTENCY UNITS

OUTCOME

The Committee agreed to make a policy decision of using the acronym of potency units in the SUSDP, where consistent with TGO 69, on the basis that this approach would promote consistency across all entries in the SUSDP.

13.1.3 GAMMABUTYROLACTONE AND 4-HYDROXYBUTANOIC ACID

DECISION 2002/35 - 14.

The Committee agrees that gammabutyrolactone (GBL) remains unscheduled at this time and the existing entry for 4-Hydroxybutanoic acid in Schedule 9 of the SUSDP remains appropriate. This decision was made on the basis that the current scheduling of 4-Hydroxybutanoic acid is consistent with the Committee's intent to exclude other derivatives of 4-Hydroxybutanoic acid, except its salts, from the requirements of

scheduling, as they being appropriately controlled through other State and Territory mechanisms.

13.1.4 PSEUDOEPHEDRINE

PURPOSE

The Committee considered the scheduling of pseudoephedrine.

BACKGROUND

Following the February and May 2000 NDPSC meetings, pseudoephedrine was rescheduled in such a way that larger pack sizes of single-active products (> 30 dosage units of 60 mg or less of pseudoephedrine) were included in S4. The majority of packs containing 30 tablets or less of single active or combination products remained in S2, although some combination products fell into S3 due to the more restrictive scheduling of other active ingredients present in the same formulation.

In November 2001, NSW made a decision to reschedule single-active pseudoephedrine products from S2 to S3, with mandatory recording of sales. This move resulted in differences in labelling requirements between NSW and the rest of the jurisdictions.

The February 2002 NDPSC meeting recognised that there was a need to address the concerns relating to the unharmonised scheduling of pseudoephedrine and agreed to consider the matter at the June 2002 meeting.

DISCUSSION

The Committee noted that pre-meeting submissions had been received from the following:

- XXXXXXXXXXXXXXX - supported the approach of treating suspicious sales of pseudoephedrine products as S3 medicine in pharmacies, with recording of purchaser's driver's license and vehicle registration.
- XXXXXXXXXXXXXXX - did not support any changes to the scheduling of pseudoephedrine and provided the Committee with the 'Code of Conduct' it had developed to prevent diversion of pseudoephedrine-containing non-prescription medicines. XXXXXXXXXXXXXXX had raised the following points in support of its position:
 - Scheduling alone would not reduce the supply of methylamphetamine to the illicit drug trade and is not an appropriate mechanism for dealing with issues of diversion.
 - Access to pseudoephedrine by legitimate customers must be maintained as there were no other equivalent alternatives available.
 - Available data was insufficient to scope the size of the diversion problem or identify the main sources of pseudoephedrine used in the illicit drug trade.

-
- XXXXXXXXXXXXXXX – did not support changes to the current scheduling of pseudoephedrine but supported a coordinated approach to the problem involving all stakeholders in an appropriate forum. XXXXXXXXXXXXXXX also stated that the Committee should encourage ownership of the problem by the industry rather than make an expedient scheduling decision that would only shift the problem.
 - XXXXXXXXXXXXXXX – supported the inclusion of pseudoephedrine in S3, on the basis of continuing problem with misuse of pseudoephedrine for the manufacture of amphetamines, in spite of voluntary restrictions by pharmacists, i.e. reports of requests for large quantities of pseudoephedrine products.
 - XXXXXXXXXXXXXXX - supported the XXXXXXXXXXXXXXX guidelines relating to the sales, marketing and promotion of both single and combination pseudoephedrine products. It stated that responsible sales and promotion of such products and limiting OTC pack sizes would reduce the problem of illicit diversion while maintaining access for legitimate users.
 - XXXXXXXXXXXXXXX – did not support changes to the current scheduling of pseudoephedrine on the basis that scheduling was not the appropriate mechanism to control the illicit diversion of pseudoephedrine. It supported the measures outlined in the XXXXXXXXXXXXXXX ‘Code of Conduct’ as being appropriate.
 - XXXXXXXXXXXXXXX – supported a coordinated approach and development of national strategies involving all stakeholders. XXXXXXXXXXXXXXX believed that scheduling was not the appropriate mechanism for controlling illicit activities and supported the application of the industry ‘Code of Conduct’.
 - XXXXXXXXXXXXXXX – believed that rescheduling pseudoephedrine to S3 was not the appropriate mechanism to control illicit activities. It suggested that an appropriate forum bringing all stakeholders together be formed for a coordinated national approach.
 - XXXXXXXXXXXXXXX – supported the national approach proposed by XXXXXXXXXXXXXXX and stated that rescheduling pseudoephedrine was not the answer to the problem of illicit use.
 - XXXXXXXXXXXXXXX – opposed further restrictions on access to pseudoephedrine and supported the formation of a stakeholder taskforce to integrate strategies for minimising the diversion of pseudoephedrine-containing products.
 - XXXXXXXXXXXXXXX – did not believe that scheduling was the appropriate mechanism to control illicit activities but supported any measure that may help control or minimise illicit activity. XXXXXXXXXXXXXXX also argued that if rescheduling was to occur, the outcome should be applied to all products containing pseudoephedrine including all combination products. It had stated that there had been confusion within community pharmacies which had resulted in restricted access being arbitrarily imposed on some combination products whilst similar products had remained unrestricted.

- XXXXXXXXXXXXXXX - believed that an appropriate schedule to encourage national uniformity in the supply of single-ingredient pseudoephedrine was Schedule 3, for consistency with the current level of pharmacist intervention already in place.
- XXXXXXXXXXXXXXX - believed that rescheduling pseudoephedrine at this time would be premature due to insufficient evidence and incomplete data available on which to base rescheduling decisions. XXXXXXXXXXXXXXX also stated that rescheduling was not likely to significantly impact on the illicit production of methamphetamine but was likely to shift the target supply source.
- XXXXXXXXXXXXXXX - highlighted the lack of uniformity in the scheduling of pseudoephedrine and stated that the best way forward was to firstly achieve national consistency in the scheduling. In addition, XXXXXXXXXXXXXXX had stated that the appropriate scheduling should take into account the drug's misuse potential while maintaining access for individuals with genuine therapeutic needs.
- XXXXXXXXXXXXXXX - had advised that the rescheduling of larger pack sizes to S4 had increased the pressure on pharmacists to sell smaller pack sizes of both single active and combination products in XXXXXXXXXXXXXXX. The XXXXXXXXXXXXXXX was concerned with the level of production of methamphetamine in XXXXXXXXXXXXXXX. On these grounds, the XXXXXXXXXXXXXXX, on behalf of pharmacists, had approached XXXXXXXXXXXXXXX seeking tighter controls on small pack sizes of both single active and combination products. XXXXXXXXXXXXXXX supported the rescheduling of pseudoephedrine from S2 to S3, to increase the ability of community pharmacists to refuse sales when considered suspicious and deter those seeking the substance for illicit use.

The Committee noted the substantial and unexplained increase in pseudoephedrine supply to Australia in 2001, as shown in the following data on pseudoephedrine Australian import statistics provided by the Treaties and Exports Section of the TGA:

Year	Year-to-date total (Grams)
2001	40,323,207.299 ¹
2000	16,101,375.844
1999	18,739,060.616
1998	11,469,471.035
1997	26,905,932.512

XXXXXXXXXXXX Members raised the following issues for consideration:

- The XXXXXXXXXXXXXXX Member proposed to reschedule single-active and combination products to S3, on the basis that both preparations were clearly being targeted in XXXXXXXXXXXXXXX for the illicit manufacture of methamphetamine.

¹ The value "40,323,207.299" was corrected to read "20,644,000" at the February 2004 NDPSC Meeting (Item 13.6)

- In XXXXXXXXXXXXXXX, only single-active products were shown to be a problem and rescheduling combination products to S3 was not supported. The member stated that this approach would result in logistical problems within pharmacies and would place an unrealistic burden on community pharmacists.
- XXXXXXXXXXXXXXX advised that it recognised similar logistical concerns when it rescheduled pseudoephedrine in November 2001 that only single-active products were moved to S3. In addition, the member informed the Committee that XXXXXXXXXXXXXXX had undertaken not to change its labelling requirements to reflect the recent scheduling change until a national decision was made.
- XXXXXXXXXXXXXXX did not support any change to the scheduling of pseudoephedrine on the grounds that scheduling was not the appropriate mechanism for controlling criminal activities. It was stated that requiring all pseudoephedrine products to be sold by a pharmacist or under the personal supervision of a pharmacist, particularly during the busy winter months, would be difficult for pharmacists and could result in complaints being made to the Pharmacy Board. It was advised that XXXXXXXXXXXXXXX had been working closely with the XXXXXXXXXXXXXXX Police and pharmacy peak bodies, and as a team had developed a mechanism for dealing with the problem of diversion of pseudoephedrine. The member stated that a hotline had been established for use by pharmacists for reporting suspicious sales of pseudoephedrine products to the police, which had assisted in the breaking of several clandestine laboratories in XXXXXXXXXXXXXXX.
- Other jurisdictions indicated that only single-active products were shown to be a major problem and that they supported the rescheduling of such products to S3. These members also stated that they shared similar concerns with regard to placing an unrealistic workload on pharmacists should all OTC pseudoephedrine be included in S3, and the potential for complaints to be made against pharmacists.

The XXXXXXXXXXXXXXX representative highlighted the following points:

- Pseudoephedrine was a legitimate and effective product with no equivalent alternative available and there was a need to balance the impact of diversion vs access by legitimate users.
- XXXXXXXXXXXXXXX pragmatically acknowledged the rescheduling of single-active products to S3 but considered any action on combination products premature and not evidence-based, given the lack of evidence/data to properly scope the issue and determine the point(s) of diversion.
- XXXXXXXXXXXXXXX was in the process of collecting national data to use as a guide in developing effective mechanisms to successfully deal with the problem. In the interim, it was proposed that the XXXXXXXXXXXXXXX approach of limiting pack sizes be adopted as a short-term measure until such time that data became available.
- The Committee should take a leading role in facilitating a forum where stakeholders could work together in developing a coordinated national approach to the pseudoephedrine problem, given that scheduling was not the full solution to the problem but only part of.

The Committee was advised that according to anecdotal evidence, XXXXXXXXXXXXXXXX was also being targeted for diversion. The member stated that the pseudoephedrine in this product was XXXXXXXXXXXXXXXX. Members noted that this formulation would not be covered under the existing definition of “compounded” in the SUSDP, which stated “*in relation to a substance combined with one or more other therapeutically active substances in such a way that it cannot be physically separated from them by simple dissolution or other simple physical means*”.

A member urged the Committee to take a pro-active approach and consider rescheduling all OTC pseudoephedrine products to S3, as there was strong evidence to suggest that both single-active and combination products were being used for conversion to illicit drugs in XXXXXXXXXXXXXXXX. The member cautioned that should the Committee only take action on single-actives and leave combination products in S2 for easier access, the problem would undoubtedly shift towards combination products and possibly leave the Committee with the same problem.

Members supported the rescheduling of single-active products in small pack sizes to S3 to achieve scheduling consistency and reflect what was already current practice in some jurisdictions where such products were already being treated as S3. In addition, the Committee agreed to review the scheduling of the remaining pseudoephedrine products in S2, and asked the jurisdictions to provide data to the October 2002 meeting on which of these products are likely to be of “high risk” and targeted for diversion. Furthermore, the Secretariat was asked to obtain data on formulation details of such products, and provide this information to the October 2002 meeting.

The Committee stated that for the purpose of defining the resulting SUSDP amendment of this meeting, the term “combination” should be used in the short term to refer to compounded and other combination products including XXXXXXXXXXXXXXXX. In addition, members also agreed to foreshadow a review of the definition of “compounded” in Part 1 of the SUSDP at the October 2002 meeting.

The Committee stated that it supported a coordinated national approach to dealing with the problem of diversion of pseudoephedrine, and that it also recognised that scheduling was not the overall solution to the problem but an integral part of a national framework of strategies designed to address the problem.

A member raised the issue that if single-active products were moved to S3 then the Committee may need to consider listing pseudoephedrine in Appendix H, on the basis that such products would no longer be allowed to be advertised if excluded.

The Committee was reminded that changes to the current scheduling of pseudoephedrine would result in an unharmonised position with NZ, and suggested that NZ-MCC be formally advised of the outcome for its consideration.

DECISION 2002/35 - 15.

The Committee agreed that based on available evidence, it would be appropriate to amend the scheduling of OTC single-active preparations, except slow release preparations, from S2 to S3. This decision was made on the basis that pharmacist intervention would help reduce the problem of diversion to the illicit drug trade while maintaining access for legitimate users. In addition, the Committee also agreed to include pseudoephedrine in Appendix H of the SUSDP to permit continued advertising.

Schedule 3 – New entry

PSEUDOEPHEDRINE in preparations (other than preparations for stimulant, appetite suppression or weight-control purposes), with a recommended daily dose of 240 mg or less of pseudoephedrine, where pseudoephedrine is the only therapeutically active substance in divided preparations containing 60 mg or less of pseudoephedrine per recommended dose in a pack containing 30 or less dosage units, **except** in slow release preparations.

Schedule 2– Amendment

PSEUDOEPHEDRINE – amend entry to read:

PSEUDOEPHEDRINE in preparations (other than preparations for stimulant, appetite suppression or weight-control purposes), with a recommended daily dose of 240 mg or less of pseudoephedrine:

- (a) in undivided preparations containing 60 mg or less of pseudoephedrine per recommended dose; or
- (b) when in combination with other therapeutically active substances; or
- (c) in slow release preparations.

Schedule 4– Amendment

PSEUDOEPHEDRINE – amend entry to read:

PSEUDOEPHEDRINE **except** when included in Schedule 2 or 3.

Appendix H – New entry

Pseudoephedrine.

FUTURE ACTION

The Committee considered the data available at this meeting insufficient to allow an assessment of the appropriateness of rescheduling the remaining S2 formulations to S3. Consequently, the Committee agreed to foreshadow a review of the scheduling of the remaining pseudoephedrine-containing products in S2 at the October 2002 meeting and sought additional data from the jurisdictions and industry on formulation details, extractability of the pseudoephedrine from the formulation, and annual sales volume (no. of units) for each formulation for the last five years.

13.1.5 HYOSCINE BUTYLBROMIDE

PURPOSE

The Committee considered the proposal to increase the dose and pack size limits for hyoscine butylbromide in Schedule 2.

BACKGROUND

Hyoscine butylbromide is a quaternary ammonium derivative of hyoscine. It acts as an anticholinergic agent and due to quaternisation of the compound it has ganglion-blocking activity. Hyoscine butylbromide reduces the tone and peristalsis of smooth muscle in hollow organs with parasympathetic innervation. Hyoscine butylbromide 10 mg tablets are currently approved in Australia for the treatment of spasms of the GI tract at the recommended oral dose for adults and children over 6 years of 20 mg, four times daily (maximum of 10 tablets per day).

The existing entry in Schedule 2 for hyoscine butylbromide specified “as the only therapeutically active substance in divided preparations for oral use containing 10 mg or less of hyoscine butylbromide per dosage unit in a pack containing 20 or less dosage units”. Hyoscine butylbromide was also listed in Appendix H (Schedule 3 Poisons permitted to be advertised) of the SUSDP.

There were 4 products containing 10 mg hyoscine butylbromide per tablet for oral use listed on the ARTG at the time of the meeting.

DISCUSSION

XXXXXXXXXXXXX submitted an application to amend the wording of the Schedule 2 entry for hyoscine butylbromide to increase the dosage per unit from 10 mg to 20 mg or less of hyoscine butylbromide, and the pack size from 20 or less dosage units to 200 mg or less of hyoscine butylbromide. This proposal was intended to accommodate the proposed product, XXXXXXXXXXXXX, containing 20 mg hyoscine butylbromide/tablet. The sponsor had stated the following justification for its proposal:

- The existing schedule permitted the sale of a pack of 20 tablets containing 10 mg or less of hyoscine butylbromide, giving a total quantity of 200 mg of hyoscine

butylbromide per pack. The proposed schedule would permit the sale of a pack of 10 tablets containing 20 mg of hyoscine butylbromide, giving a total quantity of 200 mg of hyoscine butylbromide per pack (at recommended dose of 20 mg).

- Hyoscine butylbromide had a long history of use in human medicine as an antispasmodic agent and was considered to have a wide safety margin and low overdose potential due to its relatively poor absorption following oral administration.
- Extremely rare reported side effects and adverse reactions for orally administered hyoscine butylbromide. Products were available in the XXXXXXXXXXXXXXXX as 20 mg single dose in packs containing up to 240 mg, while 10 mg tablets were available in packs of 100 (i.e., 1000 mg hyoscine butylbromide) in XXXXXXXXXXXXXXXX. Additionally, a product containing 20 mg hyoscine butylbromide per tablet was also available in XXXXXXXXXXXXXXXX.

The Committee noted the evaluation report of the company submission:

- The applicant did not provide any data to support the claims that hyoscine butylbromide had a wide safety margin and low overdose potential.
- The Drugdex Drug Evaluations monograph for hyoscine butylbromide suggested that the reported adverse events, which included CNS and cardiovascular effects, were mainly associated with parenteral and subcutaneous administration of hyoscine butylbromide at doses of 10-40 mg. The oral dose recommended by Drugdex for hyoscine butylbromide as an anticholinergic, antidysmenorrhoeal or antispasmodic agent was 10-20 mg at 3 to 5 times daily (maximum daily dose of 100 mg), for adults and children over 6 years of age. The said monograph also indicated that the absorption of hyoscine butylbromide after oral administration was limited due to the polarity of the quaternary ammonium group and low lipid solubility (estimated 8%-10% absorption of oral dose). This supported the applicant's claim that findings of pharmacokinetic studies indicated that absorption after oral administration was estimated to be 2-8% in humans and the bioavailability of oral XXXXXXXXXXXXXXXX, as calculated from plasma levels was reported to be 0.13%.
- The ARTG indicated that XXXXXXXXXXXXXXXX, containing 10 mg hyoscine butylbromide, was a 'grandfathered' product and was first registered in XXXXXXXXXXXXXXXX. The evaluator stated that the advice obtained from ADRAC indicated that there had been only 15 reports involving XXXXXXXXXXXXXXXX, from 1975 to 1999, of which 6 were linked to XXXXXXXXXXXXXXXX as the sole suspect. Of the 6 adverse reports, i.e. dizziness, mouth dryness, sepsis, urinary retention and abnormal vision, it was highlighted that none appeared life threatening.
- The applicant had quoted the use of 20 mg single-dose hyoscine butylbromide products in many overseas countries including XXXXXXXXXXXXXXXX but no safety data had been provided to support the OTC safety of these products overseas.
- The Drugdex Drug Evaluations monograph listed 'drowsiness' as a mild side effect of hyoscine butylbromide and the sponsor's submission also included a precaution that "hyoscine may cause drowsiness and patients experiencing such effects should not drive or operate machinery. Patients should abstain from alcohol." The applicant had

argued that as a quaternary ammonium compound with low lipid solubility, XXXXXXXXXXXXXXX cannot cross the blood-brain barrier easily and only rarely caused the CNS side effects associated with atropine and hyoscine (also supported by the Drugdex monograph). On this basis and that of low absorption and bioavailability of orally administered hyoscine butylbromide, there may be sufficient grounds to support the case that the potential for orally taken hyoscine butylbromide to cause drowsiness would be attenuated to a degree that requiring a sedation warning may be unnecessary.

- Drugdex also stated that infants and children were more susceptible to the effects of anticholinergics and the recommended dose for children 1-6 years of age was 7.5 mg rectally at 3-5 times daily and 7.5 mg rectally at 2-3 times daily for infants up to 1 year. The evaluator recommended that the Schedule 2 entry for hyoscine butylbromide be limited only to adults and children over 6 years of age as there was no safety data provided on oral administration to children under 6 years old.
- The evaluator noted that the maximum dosage and total amount of hyoscine butylbromide available per pack allowed in the existing S2 entry would remain unchanged should the Committee agree to the applicant's proposal. In addition, it was indicated that based on available information there was no evidence to suggest that the existing indication and dosage of oral preparations containing hyoscine butylbromide was unsafe.
- The evaluator supported XXXXXXXXXXXXXXX proposal and recommended that the Schedule 2 entry for hyoscine butylbromide be amended to "HYOSCINE BUTYLBROMIDE as the only therapeutically active substance in divided preparations for oral use in adults and children over 6 years of age, containing 20 mg or less of hyoscine butylbromide per dosage unit, in a pack containing 200 mg or less of hyoscine butylbromide".

The Committee noted that pre-meeting submissions had been received from the following:

- XXXXXXXXXXXXXXX - did not support the applicant's proposal to alter the S2 dose limit and pack size, on the basis that hyoscine butylbromide was indicated for the treatment of acute attacks of pain due to stomach or bowel cramp, and that if no relief was obtained after 48 hours the patient should consult a doctor.
- XXXXXXXXXXXXXXX – did not support the proposal and stated that there was a potential for adverse outcomes to occur as a result of consumers not recognising the changes in the formulation, which was in their view a familiar product.
- XXXXXXXXXXXXXXX – intended to comment but stated that it was unable to do so as no details on the changes had been provide in the pre-meeting notice. The company had requested the opportunity to comment on the changes upon publication of the meeting minutes.

The Committee noted that the applicant's proposal, if supported, would have no impact on the recommended dosage and pack size already allowed in the existing S2 entry.

Members noted that the evaluator had recommended to limit the S2 entry to adults and children >6 years of age, as there was no data available to demonstrate the safety of oral preparations when administered to children under 6 years of age. The Committee stated that it did not support the proposed approach on the basis that in this case, the evaluation of the product's suitability for a given age group would be undertaken at registration.

Members noted that the NZ Medsafe database did not list hyoscine butylbromide separately and suggested that NZ-MCC may need to be advised of the outcome of this consideration.

A member pointed out a discrepancy in the SUSDP where hyoscine butylbromide was still listed in Appendix H (Schedule 3 poisons permitted to be advertised). The Committee agreed that this entry should be deleted on the grounds that hyoscine butylbromide was a Schedule 2 substance.

DECISION 2002/35 - 16.

The Committee agreed to amend the Schedule 2 entry for hyoscine butylbromide to increase the dosage per unit from 10 mg to 20 mg or less of hyoscine butylbromide, and the pack size from 20 or less dosage units to 200 mg or less of hyoscine butylbromide. This decision was made on the basis of long history of safe use and no significant safety concerns had been identified with the current dosage and pack size allowed in the existing S2 entry.

In addition, the Committee agreed to delete the Appendix H entry for hyoscine butylbromide on the grounds that being a Schedule 2 substance, it is already permitted to be advertised and there is no Schedule 3 entry for hyoscine butylbromide.

Schedule 2 - Amendment

HYOSCINE BUTYLBROMIDE – Amend entry to read:

HYOSCINE BUTYLBROMIDE as the only therapeutically active substance, in divided preparations for oral use, containing 20 mg or less of hyoscine butylbromide per dosage unit in a pack containing 200 mg or less of hyoscine butylbromide.

Appendix H – Amendment

Hyoscine butylbromide – delete entry.

13.1.6 ORLISTAT

OUTCOME

The Committee agreed that the existing scheduling of orlistat remained appropriate. This decision was based on the following grounds:

- The Committee was not satisfied that the safety profile of orlistat was consistent with Schedule 3 medicines, given the wide range of contraindications and potential adverse outcomes associated with obesity.
- The Committee agreed that thorough pre-screening and assessment by medical professional for co-morbidities associated with obesity was essential to determine the patient's suitability for orlistat therapy and reduce the potential for adverse effects.
- The Committee was of the view that making orlistat for the treatment of obesity Schedule 3 medicine would impart the wrong public health message that therapeutic intervention is the first-line treatment for obesity or over-weight conditions, and could expose the public to unnecessary risks. It was stated that consumers should be encouraged to undertake the appropriate lifestyle changes as a first option to achieve safe and long-term weight loss.

13.1.7 SODIUM PICOSULFATE

PURPOSE

The Committee considered the scheduling of sodium picosulfate, polyethylene glycol (PEG) and sodium phosphate.

BACKGROUND

Sodium picosulfate, a stimulant laxative related to bisacodyl is used for the treatment of constipation, and for evacuation of the colon before investigational procedures or surgery. When taken by mouth, it stimulates bowel movements following metabolism by colonic bacteria (like bisacodyl) to the active compound bis(p-hydroxyphenyl)pyridyl-2-methane. The February 2002 meeting agreed to include sodium picosulfate in preparations for oral use for bowel cleansing prior to diagnostic, medical or surgical procedures, in Schedule 3 (from being unscheduled) on public health and safety grounds. In addition, the meeting also agreed to leave sodium picosulfate for laxative use unscheduled on the basis that there were no significant safety concerns for this indication identified at the meeting.

Polyethylene glycol (PEG) is an osmotic laxative approved for laxative and bowel cleansing use in Australia. The May 2000 meeting agreed to include in Schedule 3, macrogol 3350 (PEG) in preparations for oral use for bowel cleansing purposes, and foreshadowed the proposal to include macrogol 3350 in Appendix H at the following meeting. The August 2000 meeting did not support the listing of macrogol 3350 in Appendix H, on the basis that the Committee was not convinced that advertising would deliver health benefits to the public

Sodium phosphate in preparations for oral use for laxative or bowel cleansing purposes was first listed in Schedule 4 of the SUSDP in November 1997. However, sodium phosphate for the same indications was rescheduled to S3 in May 1999, following an appeal against inclusion in S4. The February 2001 NDPSC Meeting adopted a recommendation of the 6th Meeting of TTHWP, and rescheduled sodium phosphate for

laxative use to Schedule 4, on public health and safety grounds. Oral preparations containing sodium phosphate for bowel cleansing prior to diagnostic, medical or surgical procedures were retained in S3.

DISCUSSION

The Committee noted that a submission was received from XXXXXXXXXXXXXXXX, the distributor of XXXXXXXXXXXXXXXX bowel cleansing preparations containing sodium phosphate. XXXXXXXXXXXXXXXX proposed that sodium picosulfate, sodium phosphate and PEG be scheduled in the same way for commercial equity and on the basis of recent ADRAC adverse reports involving preparations containing sodium picosulfate. The applicant proposed the following:

- a.) retain sodium phosphate and PEG bowel cleansing preparations as S3 products;
- b.) include sodium picosulfate bowel cleansing preparations in S3;
- c.) include sodium picosulfate, sodium phosphate and PEG for laxative use in S4 (sodium phosphate for laxative use was already in S4); and
- d.) include all substances in Appendix H of the SUSDP.

The Committee noted that pre-meeting comments had been received from the following:

- XXXXXXXXXXXXXXXX – expressed interest in providing further comments.
- XXXXXXXXXXXXXXXX – requested the opportunity to comment on changes on any scheduling.

The Committee noted that there was no need to consider items a.) and b.) of XXXXXXXXXXXXXXXX proposals as the proposed outcomes were already in place. However, it was stated that there was need for further action relating to the proposal to include sodium picosulfate and macrogol 3350 for laxative use in S4 for consistency with sodium phosphate, and the proposal to include sodium phosphate, sodium picosulfate and macrogol 3350 in Appendix H of the SUSDP.

The Committee was advised that a Minute from OCM was received, indicating that there were several hundreds of products listed on the ARTG which would be classified as stimulant or osmotic laxatives.

Members noted that there were several products containing sodium picosulfate for laxative use and at least one product containing macrogol 3350 for laxative use listed on the ARTG at the time of the meeting.

It was outlined that although XXXXXXXXXXXXXXXX argued to include sodium picosulfate and macrogol 3350 for laxative use in S4 on the grounds of consistency and equity, it did not provide adequate data to support this proposal. Members highlighted that whilst it was recognised in previous considerations that there were differences in safety profiles between sodium phosphate, sodium picosulfate and macrogol 3350 for oral laxative use, laxatives in general were consistently associated with reports of being misused in the community as an aid to weight loss. On these grounds, the member

stressed that there was a strong need to undertake a safety review of individual laxatives and investigate their potential for abuse and ensure that any scheduling action taken by the Committee was supported by evidence.

OCM noted in the February 2002 NDPSC minutes that reference was made to the need for a review of the scheduling of all stimulant and/or osmotic laxatives on public health and safety grounds. OCM stated that the scheduling of ingredients in such products, as a class or individually, would have considerable implications for the future regulation of these products and could impact on the regulation of certain herbal ingredients used for other purposes. Furthermore, OCM requested that it be informed of any progress by the NDPSC or the TTHWP, in relation to the proposed review of the scheduling of stimulant and /or osmotic laxatives. The Secretariat advised that there was a wide range of unscheduled laxative products listed on the ARTG including those containing bisacodyl, lactulose, sennosides and docusate sodium.

However, in the interim the Committee agreed that the safety review of stimulant and/or osmotic laxatives foreshadowed at the February 2002 meeting was essential to resolve this issue. The Committee agreed to foreshadow the inclusion of sodium picosulfate and macrogol 3350 in Schedule 4 and seek more information, and reconsider the matter at the October 2002 meeting. In addition, the Committee also asked to have the scope of the safety review of other unscheduled stimulant and/or osmotic laxatives to be made available at the October 2002 meeting.

The proposal to include sodium phosphate, sodium picosulfate and macrogol 3350 in Appendix H of the SUSDP was considered but not supported by the Committee at the time.

The Committee was advised that the ARTG also listed other macrogols including macrogol 3400, macrogol 35000, macrogol 400 and macrogol 4000. It was proposed that the Committee consider adopting a class entry for these compounds in the SUSDP to cover all macrogols and harmonise with the NZ entry. Additionally, it was proposed that the Committee also consider including a separate entry for PEG in the SUSDP for clarity and/or cross-reference PEG to macrogols in the index of the SUSDP.

The Committee did not consider a class entry to cover all macrogols appropriate at the time, on the grounds that it was unclear as to whether the other macrogols were of the same indication as macrogol 3350, which had an entry in S3 for a specific indication. The Secretariat was asked to review the approved indications of the other macrogols listed on the ARTG and report findings at the October 2002 meeting. In contrast, the Committee supported the proposal to cross-reference PEG to macrogol 3350 in the index of the SUSDP to promote clarity.

OUTCOME

The Committee considered the available information at this meeting inadequate to make scheduling decision on the inclusion of sodium picosulfate and macrogol 3350 for oral laxative use in Schedule 4 of the SUSDP. However, it was agreed that this proposal be

foreshadowed and the matter to be gazetted for consideration at the October 2002 meeting. The Committee based this approach on the need to assess the risk profile of sodium picosulfate and macrogol 3350 for laxative use in relation to the current scheduling of sodium phosphate.

The Committee did not agree to include sodium phosphate, sodium picosulfate and macrogol 3350 in Appendix H of the SUSDP, on the basis that the indication specified in Schedule 3 was not appropriate for advertising.

FORESHADOWED

Schedule 4 – New entries

MACROGOL 3350 in preparations for oral laxative use.
SODIUM PICOSULFATE in preparations for oral laxative use.

13.1.8 POLYLACTIC ACID

OUTCOME

The Committee agreed to foreshadow the inclusion of polyacrylamide in preparations for injection for cosmetic use and tissue augmentation in Schedule 4 of the SUSDP. The Committee recognised that such uses would require administration and management of potential adverse effects by medical professionals. In addition, it was noted that this approach would achieve scheduling consistency for those products with similar uses.

FORESHADOWED

Schedule 4 - New entry

POLYACRYLAMIDE in preparations for injection:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

DECISION 2002/35 - 17.

The Committee agreed to include polylactic acid in preparations for injection for cosmetic use and tissue augmentation in Schedule 4 of the SUSDP. This decision was made on the basis that for such uses appropriate selection, safe use and management of potential adverse effects would require administration by medical professionals. In addition, the Committee noted that no regulatory impact was expected on products containing polylactic acid for other uses as a result of this amendment.

Schedule 4 - New entry

POLYLACTIC ACID in preparations for injection:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

13.2 SUSDP, PART 5

13.2.1 ERYTHROPOIETINS

OUTCOME

The Committee agreed to amend the Appendix D entry editorially in such a way that the class entry excludes all the other individual entries related to erythropoietins in Appendix D.

Appendix D, Paragraph 5 – Editorial Amendment

ERYTHROPOIETINS – amend entry to read:

ERYTHROPOIETINS **except** when separately specified in this Appendix.

13.2.2 CONIUM MACULATUM

OUTCOME

The Committee agreed to amend editorially the Appendix C entry for *Conium maculatum* to include the phrase “for therapeutic use”, and allow the supply of *Conium maculatum* plants for horticultural purposes.

Appendix C – Editorial amendment

CONIUM MACULATUM – amend entry to read:

CONIUM MACULATUM (coniine) for therapeutic use.

13.2.3 RANITIDINE

PURPOSE

The Committee considered the proposal to exempt ranitidine from WS 68, 69 and 70.

BACKGROUND

Ranitidine is a competitive antagonist of histamine H₂ receptor, and was first included in S4 following a recommendation by ADEC in 1982 to register ranitidine for the treatment of acid-peptic ulcer. In 1995, ranitidine for the short-term symptomatic treatment of

reflux oesophagitis unresponsive to conservative anti-reflux measures and simple drug therapies such as antacids was rescheduled to S3. The August 1998 meeting also agreed to include ranitidine in Appendix H.

The November 2000 meeting agreed to reschedule ranitidine for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply to S2, and amended the Appendix F, Part 3 Warning Statements (WS) to 35,68,69,70.

The following were the existing Warning Statement 35, 68, 69 and 70:

WS 35 CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful.

or CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged or excessive use without medical supervision could be harmful.

WS 68 – If symptoms persist beyond 5 days consult a doctor (or) (*dentist*).

WS 69 – If symptoms recur within two weeks of completing the course, consult a doctor.

WS 70 – Use only under medical supervision if you are taking other medicines.

DISCUSSION

The Committee noted that XXXXXXXXXXXXXXX had raised the following points in support of its application to delete WS 68, 69 and 70 for ranitidine in Appendix F of the SUSDP:

- Not compatible with the manner in which the product was used in the OTC setting;
- Potentially confusing to consumers and pharmacists;
- Did not recognise the increased awareness of the consumer in managing the symptoms of heartburn and the role of the pharmacist in monitoring and counselling consumers.

The Committee noted that the XXXXXXXXXXXXXXX application had been referred by NDPSC to the MEC meeting for comment. MEC considered WS 68 and 70 unnecessary for ranitidine but WS 69 should be amended to read “If symptoms recur within two weeks, consult a doctor”. In addition, MEC also recommended that the NDPSC consider applying the amended WS 69 to other OTC H₂-receptor antagonists, although WS 70 should be retained for cimetidine.

A member highlighted that the result of a study provided by the sponsor indicated that about 9% in the target population of heartburn sufferers were likely to require medical intervention due to recurring or persisting symptoms from the more serious cases of oesophagitis. The member emphasised that based on this finding, it was essential that the Committee provide clear directions to consumers as to when it would be appropriate to seek medical advice.

The Committee agreed that a more meaningful and simplified approach to labelling was preferred, which conveyed the message on how to use a product appropriately and directed consumers to when it was appropriate to consult a doctor. In addition, the Committee also agreed that a uniform approach would be appropriate when applying warning statements to H₂-receptor antagonists to ensure consistency across the class.

Members expressed the following views in relation to the following warning statements:

- WS 35 – the phrase which read “Prolonged use without medical supervision could be harmful” did not provide meaningful information on when it was appropriate to seek medical advice and providing clear directions in this respect would be more beneficial. Members however, agreed that retaining the warning statement relating to prolonged use of H₂-receptor antagonists in Appendix F, Part 3 remained appropriate.
- WS 68 – members concurred with the view that this warning statement could potentially confuse consumers as it was unclear whether it referred to treatment for five continuous days, or to the total of five days of using the product, given the episodic nature of the condition being treated.
- WS 69 – could be combined appropriately with WS 68 to read “If symptoms persist or recur within two weeks of completing the course, consult a doctor”.
- WS 70 – members agreed with MEC that this warning statement was unnecessary for famotidine, nizatidine and ranitidine, and that it remained appropriate for cimetidine. This assertion was made on the basis of available information and expert member advice that cimetidine was associated with significantly higher potential for drug interactions compared to other H₂-receptor antagonists.

Members supported the proposal to consolidate WS 35, 68 and 69 into one warning statement which read:

“CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist or recur within two weeks of completing the course, consult a doctor.”

A member pointed out that any amendments to the requirements in Appendix F for ranitidine, famotidine, cimetidine and nizatidine should be foreshadowed on the grounds that this matter was not included in the June 2002 pre-meeting gazette notice and that it was likely that other products would be affected.

OUTCOME

The Committee agreed to finalise the following foreshadowed amendments at the October 2002 meeting:

- Delete WS 35, 68 and 69 in Appendix F, Part 3 for cimetidine, famotidine, nizatidine and ranitidine. The Committee was of the view that a simplified approach to these warning statements, which conveyed clear directions to consumers, would provide better health outcomes.

- Delete WS 70 in Appendix F, Part 3 for famotidine, nizatidine and ranitidine, but retain WS 70 for cimetidine. The Committee agreed that based on available information, cimetidine was associated with significantly higher potential for drug interactions compared to other H₂-receptor antagonists.
- Include a requirement for WS 96 in Appendix F, Part 3 for cimetidine, famotidine, nizatidine and ranitidine. The Committee agreed that this warning statement would convey a clear message on how to use the products correctly, while providing useful directions to consumers as to when it would be appropriate to seek medical advice.

FORESHADOWED

Appendix F, Part 1 - New entry

96. CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist or recur within two weeks of completing the course, consult a doctor.

Appendix F, Part 3 – Amendments

Cimetidine – Amend entry to read:

Cimetidine when included in Schedule 3.

Warning Statement.....70,96

Famotidine – Amend entry to read:

Famotidine when included in Schedule 2.

Warning Statement.....96

Nizatidine – Amend entry to read:

Nizatidine when included in Schedule 2.

Warning Statement.....96

Ranitidine - Amend entry to read:

Ranitidine when included in Schedule 2.

Warning Statement.....96

13.2.4 STRYCHNOS IGNATII AND STRYCHNOS NUX VOMICA

OUTCOME

The Committee agreed to amend the SUSDP editorially and delete the entries for *Strychnos ignatii* and *Strychnos nux vomica* in Appendix G, and cross-reference their entries in the index to *Strychnos* spp for clarity. This decision was made on the grounds that for scheduling purposes, *Strychnos ignatii* and *Strychnos nux vomica* were already included in the entry for *Strychnos* spp, and that this approach would achieve consistency with that taken for Schedule 4. The Committee did not expect any regulatory impact as a result of these editorial amendments.

Appendix G – Editorial Amendments

STRYCHNOS IGNATII – delete entry.

STRYCHNOS NUX VOMICA – delete entry.

13.2.5 HYDROCORTISONE AND CLOTRIMAZOLE

PURPOSE

The Committee considered the inclusion of hydrocortisone and clotrimazole in combination products in Appendix H of the SUSDP.

BACKGROUND

Hydrocortisone mainly exerts a local anti-inflammatory and immunosuppressive action when applied topically and is classified as a mild potency topical corticosteroid. Hydrocortisone is available as Schedule 3 in topical creams, ointments and lotions in concentrations up to 1% for the treatment of a variety of skin disorders. The August 1998 meeting did not support the inclusion of hydrocortisone in Appendix H due to concerns that advertising may increase the potential for misdiagnosis of skin conditions and subsequent inappropriate treatment.

Clotrimazole is a broad-spectrum antifungal, which is effective in treating mucocutaneous candidiasis, *Pityriasis versicolor* and dermatophytosis. Clotrimazole belongs to the imidazole family, which exerts their antifungal action through disruption of the fungal membrane. No appreciable systemic absorption occurred with topical use of clotrimazole, which was contained in a variety of S2 formulations, at a typical concentration of 1% for the treatment of fungal skin conditions.

Hydrocortisone in preparations for rectal use and clotrimazole were listed in Appendix H of the SUSDP at the time of the meeting. The combination product of hydrocortisone and clotrimazole was being marketed as S3 medicine in a 30 g pack size, and was approved for the treatment of athlete's foot, jock itch, nappy rash, ringworm, tinea, fungal infected dermatitis and *Candida* infections.

DISCUSSION

The Committee noted that XXXXXXXXXXXXXXX stated the following points in support of its proposal to be permitted to advertise its product:

- An increased opportunity for the pharmacist to play a role in community health;
- Greater choice of effective medicines available to the public;
- The public will have more convenient access to caring for their health;
- Empowering the public to effectively treat minor inflamed, fungal skin infections; and
- Reduced cost to the public health system because the patient would not need to consult a physician.

The Committee was advised that there were existing hydrocortisone combination products available on the market containing other antifungal agents including miconazole (**S2** - XXXXXXXXXXXXXXX 0.5%, containing miconazole nitrate 2% + hydrocortisone 0.5% and **S3** - XXXXXXXXXXXXXXX hydrocortisone 1% + miconazole 2%).

A member highlighted that although clotrimazole was already listed in Appendix H of the SUSDP, its presence in a product with hydrocortisone suggested that this product was not an appropriate first-line treatment. It was stated that this combination product should only be used following a determination by the pharmacist that a fungal infection and mild skin condition treatable with hydrocortisone were both present on the skin.

The Committee was of the view that the decision of when it was appropriate to move from a single antifungal treatment to a steroid/antifungal combination was more properly made by a professional, after full assessment of the history and existing state of the infection. It acknowledged that the complexity of conveying the nuances of such a decision was difficult and may lead to inappropriate selection and use.

OUTCOME

The Committee was not convinced that advertising the combination product of hydrocortisone and clotrimazole directly to the public would provide health benefits, on the grounds that this combination product was not an appropriate first-line treatment. The Committee was mindful that advertising could promote an inappropriate message to the public that this combination product was an appropriate alternative to single-active first-line medication for treatment of fungal infections or skin conditions treatable with corticosteroids.

**14. MATTERS REFERRED BY THE AUSTRALIAN DRUG
EVALUATION COMMITTEE (ADEC)**

14.1 NEW SUBSTANCES

14.1.1 TIOTROPIUM BROMIDE

DECISION 2002/35 - 18.

The Committee agreed to include tiotropium in Schedule 4 of the SUSDP on the grounds that the condition being treated required diagnosis and management by a medical professional.

Schedule 4 - New entry

TIOTROPIUM.

14.1.2 OLAPATIDINE

DECISION 2002/35 - 19.

The Committee agreed to include olopatadine in Schedule 4 of the SUSDP on the grounds that there was no data on overseas or Australian clinical experience with what was a new therapeutic substance.

Schedule 4 - New entry

OLOPATADINE.

14.1.3 MODAFINIL

DECISION 2002/35 - 20.

The Committee agreed to include modafinil in Schedule 4 of the SUSDP on the grounds that the condition being treated required diagnosis and management by a medical professional.

Schedule 4 - New entry

MODAFINIL.

14.1.4 SULESOMAB

DECISION 2002/35 - 21.

6. The Committee agreed to exempt sulesomab for use in radionuclide imaging from the requirements of the SUSDP on the basis of the proposed use and on the grounds that there were no significant safety issues identified.

14.1.5 DROTRECOGIN ALFA

DECISION 2002/35 - 22.

The Committee agreed to include drotrecogin alfa in Schedule 4 of the SUSDP on the grounds that the condition being treated required diagnosis and management by a medical professional.

Schedule 4 - New entry

DROTRECOGIN ALFA.

14.1.6 AGALSIDASE BETA

DECISION 2002/35 - 23.

The Committee agreed to include algalsidase beta in Schedule 4 in the SUSDP on the grounds that the condition being treated required diagnosis and management by a medical professional.

Schedule 4 - New entry

AGALSIDASE BETA.

14.1.7 FONDAPARINUX

DECISION 2002/35 - 24.

The Committee agreed to include fondaparinux in Schedule 4 of the SUSDP on the grounds that the condition being treated required diagnosis and management by a medical professional.

Schedule 4 - New entry

FONDAPARINUX.

14.1.8 TRAVOPROST

DECISION 2002/35 - 25.

The Committee agreed to include travoprost in Schedule 4 of the SUSDP on the grounds that the condition being treated required diagnosis and management by a medical professional.

Schedule 4 - New entry

TRAVOPROST.

15. OTHER MATTERS FOR CONSIDERATION

15.1 HEMP AS A NOVEL FOOD

OUTCOME

4. The Committee agreed that following on from the ANZ Food Standards Council decision to retain a total prohibition on the use of hemp products in food, no action was required by the NDPSC in respect of scheduling.

15.2 NZ B3 SIGNAL HEADINGS

OUTCOME

The Committee agreed that labelling issues for harmonising scheduling of controlled substances under the NZ Misuse of Drugs Act needed to be addressed as part of the Trans-Tasman Harmonisation Program.

16. MATTERS REFERRED BY THE MEDICINES EVALUATION COMMITTEE (MEC)

OUTCOME

The Committee noted the MEC review of the Guidelines and proposals for a further review to update the *Review of Non-Prescription Analgesics*.

17. MATTERS REFERRED BY THE MEDICINES EVALUATION COMMITTEE (MEC)

MINUTES OF MCC 26TH MEETING, 11 DECEMBER 2001

17.1 FRAMEWORK FOR HERBAL MEDICINES

OUTCOME

The Committee noted that the NZ Medicines Classification Committee (MCC) had recommended adoption of the framework for herbal classification and that Medsafe had deferred further consideration pending Government decisions on the joint Australian and New Zealand registration agency for therapeutic goods.

17.2 PARACETAMOL PACK SIZES FOR EXEMPT PREPARATIONS AND LABELLING

OUTCOME

The Committee noted MCC agreement to harmonise with Australia over maximum pack sizes for unscheduled paracetamol and that this was contingent on the establishment of revised labelling agreeable to both countries.

17.3 SCHEDULING OF SR 665MG PARACETAMOL

OUTCOME

The Committee was not persuaded that the evidence presented to the Committee justified either further restriction or relaxation of the scheduling of sustained release paracetamol preparations and confirmed the inclusion of these preparations in Schedule 2.