MINUTES OF THE SECOND MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD AT 10.15 AM ON TUESDAY 19 MARCH 1985 IN THE SMALL BOARDROOM OF THE MACARTHY TRUST BUILDING, LAMBTON QUAY, WELLINGTON

PRESENT

Dr G R Boyd (Chairman)
Dr P D Bamford
Professor I R Edwards
Mr D E Buckle
Mr J H Berry
Mr R C Griffith
Mr R L Brock (Secretary)

IN ATTENDANCE

Mr R Withington
Dr K H Goh
Mrs S Combly

1. APOLOGIES

There were no apologies.

2. MINUTES OF MEETING OF 13 NOVEMBER 1984

These were accepted subject to the following amendments.

Page 3, item 6(4), line 4: replace "very" with "pharmacologically".
Page 6, item 8(1) and (2), line 1: replace "objections" with "concerns".
Page 7, item 9(3): correct "Indamide" to"Indapamide".
Page 9, item 10(4), second paragraph, line 6: delete after "...free sale".

3. MATTERS ARISING

(1) Barbiturates

Professor Edward's paper on weaning the elderly from barbiturates was tabled. The committee thanked him for providing this paper. He will amend the trade names to those in use in New Zealand. The committee suggested that the substance of the paper then be published in the Therapeutic Notes series.

At its previous meeting, the committee proposed that no new patients be prescribed barbiturates and that there should be a deadline of 31 December 1986 to make prescription barbiturates unavailable (apart from phenobarbitone). The Department of Health will meet with the New Zealand Medical Association to discuss these proposals and will report progress at the next meeting.

(2) Naltrexone Hydrochloride (Naltrexone)

Naltrexone was referred to the Drugs Advisory Committee (DAC) for consideration as to whether it should be a Controlled Drug. The DAC did not recommend control, so Naltrexone will remain a Prescription Medicine.

(3) Diphenoxylate/Atropine Sulphate Combinations (Diastop and Tolstop)

The committee was advised that Diastop has not yet been strip packaged. The Secretary will remind Pacific Pharmaceuticals of their agreement to do this and will also ask Multichem Laboratories Ltd to strip package their product Tolstop.

(4) Polymyxin B Sulphate and Bacitracin Zinc (Polysporin)

The Committee considered letters regarding the proposed re-scheduling of this product from Wellcome New Zealand Ltd, the NZ Dermatological Society, the Animal Remedies Board and the National Health Institute.

The Committee was also advised that the Animal Remedies Board has been asking the opinion of the Department of Health on the use of antibiotics in animals. They have been advised that because of the restricted use of antibiotics in human medicine, their use in animals should also be restricted.

The committee agreed that neomycin should not be available over the counter because of its sensitivity problems. It was suggested that the re-scheduling of Polysporin would create a precedent which would make any future proposed re-scheduling of other topical antibiotics more difficult to oppose. It was also suggested that in an application of this type for re-classification of a topical antibiotic, a comparison of efficacy would be useful with other prescription antibiotics and with agents currently available over-the-counter.

Members considered that the distribution of the product is not excessively limited by its current classification as a Prescription Medicine. The committee resolved not to recommend its re-classification as a Restricted Medicine.

(5) Re-scheduling of Ibuprofen (Nurofen)

The committee noted that representatives of Boots the Chemists (NZ) Ltd had visited individual members to discuss the application for re-classification of ibuprofen 200mg to Pharmacy-Only Medicine. This is inappropriate - should personal representations be necessary, these should be made before all of the committee.

The statement "...as well tolerated as paracetamol" is not acceptable as it is not supported by the confidential international statistics on adverse reactions supplied by the World Health Organisation.

The committee recommended that ibuprofen, in solid dose forms containing not more than 200 mg of ibuprofen in each dose form, should be classified as a Pharmacy - Only Medicine, subject to the condition that no ibuprofen products should bear on the packaging a statement to the effect that ibuprofen is as well tolerated as paracetamol.

This re-classification of ibuprofen will be reviewed in a year's time from the commencement of marketing as a Pharmacy-only medicine
The committee commented that ibuprofen should be packed for retail sale in safety packaging.

4. MEDICINES TO BE SCHEDULED

(1) Misoprostol (Cytotec Tablets)

This is a synthetic prostaglandin E1 analogue which inhibits gastric acid secretion. It was recommended for classification as a Prescription Medicine.

(2) Urapidil (Ebrantil Capsules and Injection)

This is an antihypertensive, which was recommended for classification as a Prescription Medicine.

(3) Bacampicillin (Penglobe)

This is a precursor of ampicillin with the same gram - positive and gram - negative spectrum. It was recommended for classification as a Prescription Medicine.

(4) Mupirocin (Bactroban)

This is an ointment indicated for the topical treatment of certain primary and secondary skin infections. It was recommended for classification as a Prescription Medicine. The committee commented that there was insufficient experience with this new product for it to be recommended for any other classification.

(5) Inosiplex (Isoprinosine)

This is an antiviral agent indicated for the treatment of various infections including herpes simplex, herpes zoster, viral hepatitis, measles and influenza. It was recommended for classification as a Prescription Medicine.

(6) Enalaprilat (Renitec IV)

This is related to enalapril. It is indicated for initial therapy in either hypertension or congestive heart failure. It was recommended for classification as a Prescription Medicine.

(7) Pipemidic Acid (Dolcol)

This is an antibiotic active against certain gram - negative bacteria. It was recommended for classification as a Prescription Medicine.

(8) Buserelin (Suprefact)

This is a synthetic analogue of the natural luteinising hormone - releasing hormone (LH-RH). It is indicated for hormone manipulation in the treatment of prostatic cancer. It was recommended for classification as a Prescription Medicine.

(9) Tolciclate (Tolmecin)

This is a topically active antimycotic agent indicated for the treatment of certain fungal infections of the skin. It was recommended for classification as a Pharmacy - Only Medicine.

(10) Zopiclone (Imovane)

This is a hypnotic agent belonging to a new chemical group, the cyclopyrrolones. It was recommended for classification as a Prescription Medicine. The committee suggested that the classification should be reviewed when there was more experience with this product.

5. MEDICINES PROPOSED FOR RE-SCHEDULING

(1) Vosol Ear Drops

The Department of Health proposed that this product be re-classified as a Prescription Medicine because of the potential ototoxicity of the propylene glycol contained in it. The committee commented that other ear drops (e.g. Xerumenex) have propylene glycol in their base. Because of the variety of products available, it is uncertain which should not be over-the-counter medicines. There is no evidence of ototoxicity in humans with products containing propylene glycol. No recommendation was made on the re-classification of Vosol Ear Drops.

(2) Nicotine Chewing Gum (Nicorette)

The committee considered letters requesting Prescription Medicine status for Nicorette from Action on Smoking and Health (ASH), the Advisory Committee on Smoking and Health, the Cancer Society of NZ Inc and a psychologist at Carrington Hospital.

The committee agreed that the unpleasant taste, long chewing time required and high purchase price would discourage the abuse of Nicorette. As a Pharmacy - Only Medicine it can be used by non-medical professionals such as psychologists who are working in the field of smoking cessation. The committee therefore did not recommend re-classification. This can be reviewed, if necessary, in a year.

(3) Imidazole Group of Anti-fungal Medicines in Vaginal Creams and Pessaries

Material supplied by Mrs G Dalziel of Christchurch was tabled. The committee considered that because of the difficulty of diagnosis of sexually transmitted diseases and other vaginal conditions, the patient should see her doctor before medication was obtained. The Prescription Medicine classification should therefore be retained.

(4) Procaine Hydrochloride (Aslan GH3)

The commiteee did not accept that procaine hydrochloride is a vitamin precusor. It was suggested that New Zealand New Image Ltd should make a New Medicine Application for Aslan Super (GH3) as their correspondence mentioned altering a metabolic process for a therapeutic purpose. Evidence of efficacy should be provided with this application. No change to the classification of procaine hydrochloride was recommended.

(5) Undecenoic Acid (Pedisan and Mycota)

A letter had been received from the Boots Company (NZ) Ltd stating that Pedisan is now classified as a Pharmacy - Only Medicine although it was formerly on the Permitted Sales List. The Secretary was asked to determine when undecenoic acid was added to the formula as this may not have been present when the product was available on free sale. He will also provide details on the level of boric acid and the formulations of comparable products. Further consideration was deferred until the next meeting.

6. AMENDMENTS TO THE SCHEDULES OF THE MEDICINES REGULATIONS

(1) Theophylline for Parenteral Use

The committee supported the suggestion by the Department of Health that theophylline for parenteral use should be classified as a Prescription Medicine.

(2) Triclosan

The committee agreed that the entry under Pharmacy - Only Medicines should read : "Triclosan, in medicines containing more than 1 percent of triclosan".

This exempts Clearasil Skin Coloured Medication and Clearasil Vanishing Medication, which formerly appeared in the Permitted Sales List.

7. ANALGESICS

(1) Aspirin, Paracetamol and Ibuprofen

The committee noted that there were no reports from New Zealand associating Reye's Syndrome with aspirin. The Medicines Assessment Advisory Committee has recommended that aspirin not be given to children under 5 years, but this was not particularly because of a possible risk of Reye's Syndrome but in view of potential gastric effects. Reye's Syndrome was therefore not an influence in the committee's deliberations on the possible re-scheduling of aspirin on safety grounds.

It was proposed that both aspirin and paracetamol should be available on open sale with restrictions on pack size and dose, but the committee could not reach agreement on this. It was agreed that it would be impractical to withdraw aspirin entirely from open sale because of its long tradition of availability.

The committee will study in one year's time the proposal that aspirin, paracetamol and ibuprofen go on open sale in limited pack size and dose size. A pack size of ten was suggested.

The Secretary will request figures for the number of tablets of these analgesics produced in New Zealand. These will be obtained from Intercontinental Medical Statistics (NZ) Ltd and the manufacturers of aspirin.

(2) Codeine

The committee suggested that further restrictions on the legal use of codeine were unlikely to have much effect on its illegal use. Currently efforts are being made to control pyridine which is essential in the synthesis of "home-bake" morphine. The committee did not support the recommendations of the Drugs Advisory Committee that all codeine sales be registered and that the retail pack size be limited to 24 tablets or capsules. The committee considered that it would be impractical to record every sale of codeine and that desperation in the abusers would lead them to violence against pharmacists and into abuse of more dangerous substances.

(3) Dextropropoxyphene

The committee considered that this is a less suitable analgesic than those named above. It is abused to a small extent. There is a danger in overdose. Dextropropoxyphene will be referred to the Medicines Assessment Advisory Committee for reconsideration of its efficacy and safety.

8. OTHER BUSINESS

(1) Deputy Chairman

The committee resolved that in the event of Dr Boyd's absence, Mr Griffith should act as Chairman.

(2) Labels on Bottles

The National Poisons Centre has received a letter complaining about the size of writing on medicine bottles. Dr Boyd agreed to reply to this.

(3) Nabilone Capsules

This substance is not covered under tetrahydrocannabinol as a Controlled Drug. A prescription form for nabilone has been received by the Department of Health, although an application

for consent to its distribution was declined. It was probably supplied to a named patient in accordance with the Medicines Act - the Department will follow up on this.

The meeting closed at 4.15 pm.

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