

MINUTES OF THE THIRD MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE, HELD AT 10.15 AM ON TUESDAY 17 SEPTEMBER 1985 IN THE BOARDROOM OF THE MACARTHY TRUST BUILDING, LAMBTON QUAY WELLINGTON

PRESENT

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

IN ATTENDANCE

Dr R C Riseley (items 1-4 (3) only)  
Mrs C Van Der Lem  
Mr J Pine  
Mr R Withington  
Mrs S Comby

1 APOLOGY

An apology for absence was accepted from Dr G R Boyd

2 DATES OF MEETINGS FOR 1986

Dates for the next two meetings were agreed as 11 March and 16 September 1986.

3 MINUTES OF THE MEETING OF 19 MARCH 1985

These were accepted subject to the following amendments:

Page 1, item 2 last line, delete "free"  
Page 1, item 3, amend "Edwards"  
Page 2, item 3(1), 4th line, change "prescription" to "oral"  
Page 3, item 3(5), add to 4th paragraph "from the commencement of marketing as a Pharmacy - only Medicine"  
Page 5, item 5(1), delete final sentence and replace with "It was recommended that Vosol not be reclassified".  
Page 5, item 5(4), 2nd line, amend "precursor"  
Page 6, item 7(1), 1st paragraph 7th line, delete "gastric effects" and replace with "effects on acid/base balance in young children"  
Page 7, item 7(1), delete 1st paragraph and replace with:  
"In one year from the commencement of marketing of ibuprofen as a Pharmacy - only Medicine, the committee will reconsider the classification of aspirin, paracetamol and ibuprofen".

4 MATTERS ARISING

(1) Barbiturates

The Deputy Chairman stated that Professor Edwards' paper will be revised and published in the second quarter of 1986.

Dr Riseley commented that no meeting had yet been held with the New Zealand Medical Association to discuss the committee's proposal that oral barbiturates be made unavailable by 31 December 1986. He presented data showing that prescriptions for barbiturates continue to decline, but deaths continue at 5 or 6 per year - nearly all of which are suicides. There is a core of both patients and prescribers involved in the use of barbiturates.

The committee resolved that the pharmaceutical companies Eli Lilly (NZ) and Co and May and Baker (NZ) Ltd should be written to in order to advise them of the proposal and to seek their views. The letter would state that sedative and hypnotic oral barbiturates are outdated, consistently contribute to drug related deaths in New Zealand and are still abused in spite of all the measures taken in recent years. Abuse figures will be annexed.

The College of General Practitioners will also be asked for their comments. The issue will then be raised in the Clinical Services Letter or as a footnote to Professor Edwards' paper in the Therapeutic Notes series. Mention will be made that psychological dependence can last for two years following cessation of use. A schedule will be drawn up after the manufacturers' comments have been examined at the meeting of March 1986.

(2) Undecenoic acid (Pedisan and Mycota)

The committee examined the history of these products in New Zealand. It was noted that both undecenoic acid and dichlorophen can cause sensitisation, although not to the same extent as boric acid. The committee resolved not to recommend any change in the classification of undecenoic acid or dichlorophen.

(3) Nabilone

The committee noted that there is a potential for abuse with this substance and resolved to refer it to the Drugs Advisory Committee for consideration as a controlled drug.

If it does not become a controlled drug, a Prescription Medicine classification will apply.

(4) Codeine

Dr Riseley commented that there had been little change in the situation with "homebake" morphine, with about 20 new patients treated at the Auckland centre each month.

It had not proved possible to restrict the availability of pyridine, which is used in the synthesis of morphine from codeine. He will report on sales figures of codeine at the next meeting.

5 NEW MEDICINES TO BE CLASSIFIED

(1) Piretanide (Arelix)

This is a diuretic and antihypertensive. It was recommended for classification as a Prescription Medicine.

(2) Penbutolol (Betapressin)

This is a beta-blocking agent used in the treatment of hypertension and heart diseases. It was recommended for classification as a Prescription Medicine.

(3) Pramoxine hydrochloride (Proctofoam H.C.)

This medicine has anti-inflammatory, antipruritic and anaesthetic properties and is for perianal application.

Pramoxine was recommended for classification as a Pharmacy - only Medicine in medicines for external use (Proctofoam will be a Prescription Medicine because of its hydrocortisone content).

(4) Nitrous oxide

This is an anaesthetic gas, which the committee recommended for classification as a Prescription Medicine.

(5) Bifonazole (Mycospor)

This is an antifungal agent which is indicated for the treatment of dermatomycoses. It was recommended for classification as a Pharmacy - only Medicine when used in dermatological preparations and as a Prescription Medicine otherwise.

(6) Interferon alpha - 2 (Intron)

This is an antiviral, antiproliferative and immunomodulatory agent which is indicated in the treatment of AIDS - related Kaposi's sarcoma. Interferons were recommended for classification as Prescription Medicines.

(7) Tenoxicam (Tilcotil)

This is a non steroidal anti-inflammatory agent indicated for the treatment of painful inflammatory and degenerative diseases of the musculoskeletal system. It was recommended for classification as a Prescription Medicine.

(8) Aescin (Reparil Gel) and

(9) Diethylamine salicylate (Reparil Gel)

Reparil gel is an anti-inflammatory, pain relieving aescin-heparinoid gel which combats swelling and oedema. Both of the above active ingredients were recommended for classification as Pharmacy - only Medicines.

(10) Propofol (Diprivan)

This is a short acting intravenous anaesthetic agent suitable for the induction and maintenance of general anaesthesia. It was recommended for classification as a Prescription Medicine.

(11) Bepridil hydrochloride (Cordium)

This is a calcium antagonist which is indicated for the treatment and long term management of angina pectoris. It was recommended for classification as a Prescription Medicine.

(12) Lisuride hydrogen maleate (Dopergin)

This inhibits the release of the hormone prolactin and is indicated for the elimination of dopamine deficiency symptoms. It was recommended for classification as a Prescription Medicine.

(13) Oxaprozin (Duraprox)

This is a long acting nonsteroidal anti-inflammatory agent with analgesic and antipyretic properties. It is indicated for relief of rheumatoid and acute gouty arthritis, osteoarthritis, ankylosing spondylitis and musculoskeletal disorders. It was recommended for classification as a Prescription Medicine.

(14) Lipase, protease, amylase (Cotazym)

These are digestive enzymes derived from porcine pancreas which are used as a supplement in pancreatic deficiency states. The committee recommended that these enzymes should not be classified.

(15) Gemfibrozil (Lopid)

This is a lipid regulating agent which lowers elevated serum lipids. It was recommended for classification as a Prescription Medicine.

(16) Betazolol hydrochloride (Betoptic)

This is a miotic agent used to lower intraocular pressure. It was recommended for classification as a Prescription Medicine.

## 6 SUBSTANCES NOT PREVIOUSLY SCHEDULED

(1) Calcium carbimide (Dipsan)

This provokes an unpleasant challenge reaction with alcohol and it is used in the treatment of chronic alcoholism. It was recommended for classification as a Prescription Medicine.

(2) Tramadol (Tramal)

Schering (NZ) Ltd had forwarded papers on this analgesic so that the committee could give them an indication as to its probable classification. The committee noted that the human study reported was on cancer patients. Substantially more reports relating to dependence and tolerance were required, especially in the countries where it is marketed to allow a recommendation to be made. Otherwise the committee would refer tramadol to the Drugs Advisory Committee.

for consideration for Controlled Drug status.

## 7 MEDICINES PROPOSED FOR RE-CLASSIFICATION

### 1) Selenium sulphide 1 percent (Selsun)

This substance is covered by the Medicines Regulations 1984, Amendment Number 1. The committee did not therefore discuss it further.

### 2) Diclofenac (Voltaren Emulgel)

This is a topical formulation of the non steroidal anti-inflammatory agent. The committee requested more information on contraindications and photosensitisation with a view to reconsidering its classification.

### 3) Silver Acetate ("Call It Quits")

This is a mouth spray which is promoted as a smoking deterrent. The committee agreed that it required a submission from the distributors of "Call It Quits" to allow consideration, as there were insufficient data in the material supplied by the Department of Health to the committee.

## 8 PROCESSING OF AMENDMENTS TO MEDICINES REGULATIONS

The Secretary reported that Amendment Number 1 to the Medicines Regulations 1984 had been gazetted on 12 September. This contains the classifications recommended by the first and second meetings of the committee. The delay resulted from a low priority given to its legal drafting. The committee considered that the delay in the implementation of its recommendations was outside the acceptable period. The committee deliberates on significant matters to do with new medicines and when accepted by the Minister, its recommendations should be given effect promptly. Two amendments should be produced each year.

## 9 GENERAL BUSINESS

### (1) Teldane

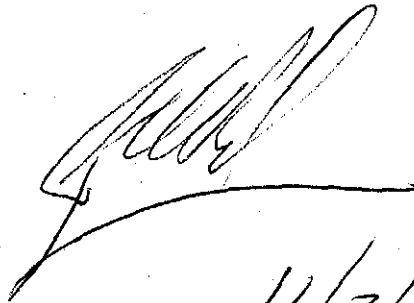
Mr Berry had noted that Teldane is exempted from the statutory warning statement for antihistamines. Mr Griffith commented that this was accepted by the Medicines Assessment Advisory Committee (MAAC) - a modified statement is required in the package insert. Professor Edwards added that he had received reports of drowsiness with this medicine through the World Health Organisation. The MAAC had been concerned that the distributors would not market this medicine if the standard warning was used and it was a significant advance over other antihistamines.

A modified warning statement had therefore been agreed to.

(2) Yogurt

Mr Buckle expressed concern at the recommended use of yogurt to treat vaginal thrush in Health Magazine (volume 37 number 2). There is a need for a medical diagnosis and not self diagnosis for this condition. The committee's concern will be expressed to the editor.

THE MEETING CLOSED AT 12.30 PM

A handwritten signature in black ink, appearing to be 'P. Buckle', written in a cursive style.

11/3/86