



Department of Health,
P.O. Box 5013,
Wellington.

27 May 1983.

CLINICAL SERVICES LETTER NO. 218

To Medical and Dental Practitioners

(Copy to Proprietors of Retail Pharmacies)

IS ONE OF THESE YOURS?

- | | Interpreted as |
|---|----------------|
| 1. 3.6 mg promethazine hydrochloride
9 mg codeine phosphate
7.2 mg ephedrine hydrochloride } 5 ml | |
| 2. LUPOCIN 25g 1000 mg 500 mg | |
| 3. Keps Kudoed
1 Lg 1000 mg | |
| 4. Dinitr in 1 ball | |
| 5. I Repara
4 L 1000 mg | |

LIBRARY
DEPARTMENT OF HEALTH
WELLINGTON

6.

Aconite, belladonna, and chloroform
liniment (Lin ABC)

Shane
man of the
my home

7.

To the
4 30

8.

Progynova 1 mg

To be continued

9.

Bendrofluazide 2.5 mg

17 to be 2.5
1730 2.5

The above examples illustrate the dangers of illegibly written prescriptions. Surprisingly, the patient's name (including whether Mr, Mrs, or Miss) sometimes proves more difficult to decipher than the name of the medicine, its strength, dosage, and the quantity to be dispensed. The importance of writing all prescription details clearly can not be overemphasised.

QUALITY CONTROL OF MEDICINES IN NEW ZEALAND

New Zealand's "Code of Good Practice for Manufacture and Distribution of Medicines" is based on, and adopts the Code of the World Health Organisation and is used as the guideline when the Division of Clinical Services inspects local manufacturers of medicines or inspects the submitted data concerning imported medicines. In the case of imported medicines we

rely largely on the fact that similar inspections are carried out in the country of manufacture and WHO certificates of quality are available from the competent authority in the exporting country.

Inspections

All 75 manufacturers of medicines and related products are inspected annually, with the manufacturers of parenteral products being visited every 6 months.

The inspection includes all aspects of the operation: buildings, equipment, manufacturing and packing procedures, documentation, laboratory facilities, and quality control systems. Defects are discussed with the firms and a written report is subsequently sent to them.

It is intended that, soon, all medicine manufacturing plants will be licensed and a satisfactory inspection will be a requirement for maintenance of that licence.

Monitoring of Quality (The Mediquial Programme)

A testing programme designed to look at therapeutic groups of medicines is planned from year to year. Chemistry Division of the Department of Scientific and Industrial Research performs the chemical analyses and the National Health Institute carries out microbiological testing.

This programme is regularly disrupted by urgent testing of medicines which have been the subject of a complaint or a problem. Priority is given to "complaints" about medicines which form an integral part of the monitoring of quality.

Defects and Recalls

The results of testing are normally made available to the manufacturer or agent with a request for an explanation of any defect or failure to comply with specifications. Where the defect is sufficiently serious the firm is requested to recall that particular batch. Depending on the potential danger, recalls may be to wholesale or hospital level, to retail pharmacy level, or ultimately to doctor and individual patient level when the problem is potentially life-threatening.

The laboratories test annually some 200 products, which in 1982 included 90 that were the subject of a complaint.

Recalls were requested for 20 products because of defects found in the regular testing programme or following a complaint. Fifteen were to wholesale and hospital level and 5, of a more serious nature, were extended to retail pharmacy.

Problems which have led to recent recalls include bottles found to contain wrong tablets, tablets packed in wrong safety packaging foil, a wrong formulation used for a cream which leads to reaction with aluminium tubes, incorrect labelling of ampoules where a product did not carry a warning required by the BP, and bottles where a wrong label had been used.

If there is reason to suspect the quality of any medicine, forward details, including the batch number, if possible, with samples to the Director of Clinical Services, P.O. Box 5013, Wellington.

SAFETY OF PRIMARY FIRST AID DRESSINGS AND BANDAGES

All of the above products supplied for retail sale in New Zealand are now being sterilised after importation or on completion of manufacture if made in this country.

Some items not likely to come into contact with an open wound have been exempted from this requirement, including triangular bandages, adhesive tape, crepe bandages, tubular bandages, and gauze.

Bacterial Contamination

In some overseas countries bandages sourced from Asia were found to carry microbiological contamination with possibly pathogenic organisms, notably clostridial species. In fact, we have established that there is a potential hazard in this respect with products from any country if they are processed or handled in less than ideal conditions. Also much of the material labelled as of European origin is originally woven in an Asian country before being finished and packaged with well known brand names in Europe.

The Current Position

Primary first aid dressings and bandages for retail sale will undergo a sterilisation procedure after importation or on completion of manufacture if made in New Zealand. Because these products are not wrapped to maintain sterility this will do no more than reduce any possible risk of infection from them.

Sterile first aid dressings and bandages will be available for purchase in a range of products, wrapped to maintain sterility and clearly labelled "sterile" or words to that effect.

In order that hospitals offer no lesser safety to their patients than the public receives from retail outlets, it will be necessary for them to either purchase supplies which have undergone a sterilisation procedure or arrange for their own sterilisation of all items before use.

Recommendations

For application on open wounds the safest product to use is one labelled as "sterile" which has been correctly stored and has an intact wrapper. Dressing wounds with other products must always have some slight risk of infection, but this risk is increased when an unsterile product such as gauze is stored in opened packets and then used as a wound dressing. Such a practice can no longer be recommended.

DIRECT GENERAL PRACTITIONER REFERRALS TO HOSPITALS OUTSIDE THE LOCAL HOSPITAL BOARD AREA

General practitioners are reminded that if patients are referred directly to hospitals under the control of another Board, they cannot expect travel expenses to be met by the "owner" Board. If assistance to meet expenses is required the referral should be arranged through the "owner" Board. Such expenses may occasionally be considerable as in the case of referrals to the Spinal Injuries Unit.

INTENSIFIED ADVERSE DRUG REACTION REPORTING SCHEME

Mianserin (Tolvon), a tetracyclic antidepressant medicine, already available on the market, is to be added to the scheme. Clinical Services Letters Nos 212 and 214 included warnings of white cell depression related to the use of mianserin. As further cases are being reported, both in New Zealand and overseas, it has been considered that additional data on the safety of use of mianserin would accrue from its inclusion in the IADRRS. It has also been reported that mianserin is less likely to be hazardous in an overdose situation than other antidepressants.

Blood monitoring should be carried out on all patients receiving mianserin. As the onset of white cell depression may be sudden, a previous normal count cannot be depended upon and the occurrence of clinical symptoms of pyrexia, headache, or sore throat calls for further immediate checking.

All adverse events, not just blood dyscrasias, should be reported as usual to the Medical Assessor, P.O. Box 913, Dunedin.

From 1 June 1983 the list of medicines included in the scheme will be:

Acyclovir (Zovirax)
Amiodarone hydrochloride (Cordarone-X)
Captopril (Capoten)
Mianserin (Tolvon)
Nifedipine (Adalat)
Tocainide hydrochloride (Tonocard)

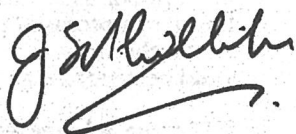
LIST OF SPECIALISTS

The following are recognised as specialists for the purposes of the Drug Tariff and Health Benefits only. These additions cover the period from 1 December 1982 to 22 April 1983.


- | | |
|------------------------------------|-------------------------------------|
| *ACLAND, Richard Hugh, AN | *JACKSON, Rodger, RAD/D |
| *ANDERSON, Kenneth Ritchie, PATH | *JAMIESON, Murray Grenfell, O/E |
| *ANSELL, David Alan, O/G | *KINGHAM, Rosemary Anne, AN |
| BLAKE, Peter, S/OTO | *LOGAN, Andrew John, OPH |
| *BOTICA, Flora, PSYC | MACFIE, Andrew Egerton, IM |
| BROWN, Stuart Whitaker, S/GEN | *MALCOLM, Laurence Allan, CM |
| *BURRY, Alastair Fleet, PATH | *MELLSOP, Graham Wilfred, PSYC |
| *CALHAEM, Malcolm Noel, AN | *MOORE, Timothy Eisdell, RAD/D |
| *CHURCH, James Michael, S/GEN | *MURRAY, Jonathan Aiden Muir, |
| *CRABB, David John Mackenzie, S/PL | S/OTO |
| *CRONE, Peter Denholm, AN | OCKELFORD, Paul Anthony, PATH |
| *CUTFIELD, Geoffrey Ronald, AN | *PETTIT, John Ewart, PATH |
| *DURING, Zoe Petronella, CM | *PHILLIPS, Frederick Jurgen, S/OR |
| *EARNSHAW, Ellis Ross, OPH | PRYOR, Peter John, AN |
| *EDWARDS, Ivor Ralph, IM | ROGERS, Walter James Blachford, |
| *FERNER, Geoffrey Noel, VD | PSYC |
| *FINLAY, Kelvin Robert, OPH | *ROMERIL, Kenneth Robert, IM, |
| *FONG, David Tay Sang, RAD/D | PATH |
| *GOLDSTRAW, Paul William, IM | *SAGE, David John, AN |
| *GRENFELL, Richard Stanley, AN | *SEEMAN, Hildegard Margaret Ingrid, |
| *GUPTA, Raj Kumar, PATH | CM |
| *HEINZ, Colin Angus, AN | *SINCLAIR, Stewart William, S/PL |

*SPIERS, Andrew Duncan, AN
*STOKES, John William, AN
SULLIVAN, John Martin Patrick,
S/OR
*TURNER, Douglas James, S/OR
TYLER, James Rowland, S/GEN
WAREING, Christopher Robert,
PSYC

*WHITTLE, Denis Edward, S/GEN
*WILKINSON, Michael Robert,
RAD/D
*WILSON, Janice Marjorie, PSYC
WILSON, Leona Fay, AN
*YOUNG, David William, DER



J. S. Phillips,
Director.



G.R. Boyd,
Deputy Director.

Division of Clinical Services.