



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

8 June 1979.

CLINICAL SERVICES LETTER No. 187

To Medical and Dental Practitioners

(Copy to Proprietors of Retail Pharmacies)

MEDIQUAL PROGRAMME

During the 1960s the first quality testing of medicines available on the New Zealand market was carried out by the DSIR at the request of the Division of Clinical Services. This first venture covered cough mixtures and the results were published in 1969.

It was however in 1972 that moves were made to put this programme on a more solid and continuing basis and a joint programme was arranged between the Division of Clinical Services, DSIR and the National Health Institute. Since that time the programme has been steadily widened in scope and joint meetings are now held twice yearly for the purposes of discussing problems and arranging areas to be tested. In the early years testing was largely chemical but biological testing is also now becoming increasingly available.

Under the terms of the Food and Drug Act 1969 no medicine may be sold or distributed in New Zealand until the consent of the Minister of Health has been notified in the *Gazette*. Before such a "consent" is granted every medicine is assessed in the Division of Clinical Services with the assistance of the Drug Assessment Advisory Committee. Such assessment is comprehensive and includes thorough investigation of the quality standards for manufacture of the product before it is released on the market.

Once marketing has commenced, the continuing quality of those products, which are manufactured in New Zealand, comes under further surveillance by the Division of Clinical Services through its pharmaceutical manufacturing inspection programme against requirements of the New Zealand Code of Good Manufacturing Practice. Every factory in New Zealand is inspected at least once a year and the standards expected are of a high level.

However, the final proof of the continuing quality of medicines available on the New Zealand market (both locally manufactured and imported) can only come from testing of the product as available on the market. The Mediquel programme for monitoring quality now has a two pronged approach:

1. A random testing programme whereby all those available products of selected therapeutic groups are tested during a particular year.
2. A trouble oriented programme directed at those areas where complaints have been received or where experience, whether locally or overseas, has indicated that problems may exist (e.g., long acting aspirin preparations).

Samples are purchased on the market, usually from wholesalers, but it is intended in the future to collect more samples from retail shops. In some situations, as when testing intravenous fluid preparations, the physical bulk of the sampling is in itself a problem. Testing then proceeds against the up-to-date standards which have previously been obtained from the manufacturers or distributors. In the case of overseas products the local major distributors are now expected to be aware of the specifications of all products they handle and to have them available on request.

Those batches of products which fail to meet their specifications are usually recalled from the market unless the problem is a very minor one. Such a recall is usually either to wholesale or to retail level depending on the importance of the fault, but in a case of danger to the patient could be required to patient level. This is one of the main reasons why batch numbers are now being required on all medicines.

In New Zealand there is now an average of 20 to 25 such recalls in any 1 year. It should be emphasised that no instance of serious danger to patients has occurred and in these circumstances there is normally no publicity beyond the wholesale or retail area. This is important as usually only one batch of a particular product is involved and the reputation of the product as a whole is not in question.

During 1978 recalls which took place included the following reasons:

1. Fishy taste.
2. Low number of doses, low assay, brown residue.
3. High particle counts in I.V. fluids.
4. Mix of different tablets in same bottle.
5. Contamination of antibiotic syrup with *Klebsiella pneumoniae*.
6. Low assay in topical solutions.
7. Label errors.
8. Particulate matter in infusion.
9. Precipitation in cough mixture.
10. Presence of chemicals not in formula.
11. Irritation by eye drops due to container.
12. Blue colouration of antacid.
13. Black specks in creams due to internal lacquer on tube.
14. Foreign bodies in antibiotic syrup.
15. Low assay in hormone preparations.
16. Low solubility in dissolution testing.

The flush of new medicines which appeared on the market 15 to 20 years ago has led to the recent and impending expiry of a number of patents. This in turn is leading to the appearance of a number of generic products on the market, many of them cheaper in price than the original patented products. Such generic products are subjected to careful scrutiny before marketing and bioavailability information is always required where relevant. These products are also subjected to continued testing to ensure that standards are consistent. It would be fair to say that recalls are occurring equally among products from the research-based traditional manufacturers and those from generic manufacturers. In fact, of course, some research-based manufacturers are now also taking part in generic manufacturing.

Any practitioner who has reason to suspect the quality of any medicine is requested to forward details and samples to the Director of Clinical Services, P.O. Box 5013, Wellington.

APPOINTMENT OF DEPUTY DIRECTOR—DR J. S. PHILLIPS

The appointment of Dr Phillips as deputy director, Division of Clinical Services has been confirmed.

Dr John Phillips joined the department as a visiting medical practitioner in 1972 after 22 years experience in general practice at Auckland, Wairoa, and Matamata. In January 1975 he was promoted principal medical officer with special responsibilities for the drug tariff and the evaluation of new medicines. He became assistant director in 1978.

In his new post Dr Phillips is in charge of the medicines control section and, while other medical appointments in the division remain vacant, will also be involved with the medical benefits side, particularly with general medical benefits, maternity benefits, and the practice nurse scheme.

OVERSEAS VISITORS—ELIGIBILITY FOR NEW ZEALAND HEALTH BENEFITS

Health benefits under Part II of the Social Security Act are available to visitors to New Zealand from the United Kingdom, apart from seamen. Visitors from all other countries must meet the full cost of any medical, hospital, and related treatment they receive while in New Zealand.

Practitioners attending an overseas patient who is not entitled to New Zealand health benefits should obtain payment for the full fee from the patient. No claim should be made for GMS benefits. If the practitioner operates under the refund system the receipt should be annotated to indicate that the patient is not entitled to a social security refund. These overseas patients are also not eligible for free medicines and this should be indicated on the prescription.

In addition to visitors from the United Kingdom, a person from any overseas country who intends to stay in New Zealand for at least 2 years and who has the legal right to do so, is also entitled to health benefits while resident here.

NEW ZEALAND VISITORS—ELIGIBILITY UNDER THE BRITISH HEALTH SERVICE

Following some recent inquiries concerning the entitlement of New Zealand visitors under the National Health Service, clarification of the position has been obtained from the United Kingdom authorities. New Zealand visitors can receive free medical attention in the United Kingdom but only when it is required *urgently*. Only emergency treatment is available free to New Zealand visitors. This has been defined as "treatment which becomes immediately necessary during a visit to the United Kingdom either as a result of an accident or illness, or for the unexpected exacerbation of a pre-existing condition where treatment could not await the patient's return home." If treatment is not of an emergency nature the full cost would have to be met by the patient, including the cost of the consultation.

Visitors requiring emergency treatment should be advised to check with the doctor or hospital authority that the service is to be provided free under the National Health Service.

INTENSIFIED ADVERSE DRUG REACTIONS REPORTING SCHEME

The number of reports being received under this scheme has been falling. The list of medicines involved has recently been reviewed and it is considered that continued monitoring of the same medicines would be advisable. Practitioners are particularly requested to continue forwarding to Professor McQueen any reports of adverse drug reactions or unexpected events which occur during therapy with the following medicines.

Acebutolol hydrochloride (Sectral)
Atenolol (Tenormin)
Cefoxitin (Mefoxin)
Cimetidine (Tagamet)
Labetalol hydrochloride (Trandate)
Metoprolol tartrate (Betaloc, Lopresor)
Sotalol hydrochloride (Sotacor)
Perhexiline maleate (Pexid)
Sodium valproate (Epilim)

A. G. Scott

(A. G. Scott)
Director,

J. S. Phillips

(J. S. Phillips)
Deputy Director,

Division of Clinical Services

NEW ZEALAND CANCER CONFERENCE—WELLINGTON

Incorporating the Annual Scientific Meeting of the Society for Oncology

11-15 SEPTEMBER 1979

This Conference will be held in the Wellington Clinical School of Medicine and will cover different aspects of the care of patients with cancer, together with recent advances in the field of research and treatment.

Invited Overseas Speakers include:

Professor G. Adams: Biochemist, Institute of Cancer Research, The Royal Marsden Hospital, London.

Mr M. Baum: Reader in Surgery, Kings College Hospital, London.

Dr A. Coates: Medical Oncologist, N.S.W. State Cancer Council Special Unit, Sydney, Australia.

Mr N. Davis: Surgeon, Director, Queensland Melanoma Project, Australia.

Dr Sylvia Lack: Hospice Director, Newhaven, Connecticut U.S.A.

Dr J. Stjernsward: Director, Ludwig Institute for Cancer Research, Berne, Switzerland.

Professor M. Tattersall: Director, Ludwig Institute for Cancer Research, Sydney, Australia.

Professor Sydney Salmon: Professor of Medicine, University of Arizona Cancer Center, Tuscon, Arizona U.S.A.

Programme:

11 September—Seminar on Continuing Care of Cancer Patients.

12–13 September—Clinical Oncology. Sessions devoted to: 1. Breast Cancer, 2. Recent advances in Oncology, and 3. Clinical Trials.

13–14 September—Workshop on Cancer Research.

15–15 September—Scientific Meeting of NZ Society for Oncology.

15 September—National Mastectomy Rehabilitation Seminar.

This Conference is supported by the Cancer Society (Wellington Division).

Inquiries to: Christine Stanley, Department of Radiotherapy and Oncology, Wellington Hospital, Private Bag, Wellington.