Department of Health,
P.O. Box 5013,
Wellington.
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CLINICAL SERVICES LETTER No. 165

To Medical and Dental Practitioners

(Copy to Proprietors of Retail Pharmacies)

INTENSIFIED ADVERSE DRUG REACTION REPORTING SCHEME

It is now accepted that despite the very full investigation and assessment which is required before a new medicine is given consent to market, severe and unexpected reactions may not always become apparent in the pre-marketing phase and indeed may not be recognised until some years of post-marketing experience have ensued. Prominent examples have been thalidomide and practolol.

An Intensified Adverse Drug Reaction Reporting Scheme is now being commenced in the hope that earlier identification of such reactions will result. This scheme has been arranged by the Department of Health acting on the recommendation of the Drug Assessment Advisory Committee and with the full co-operation and advice of the Committee on Adverse Drug Reactions and the Pharmaceutical Manufacturers Association.

All practitioners, in both private and hospital practice, are asked to co-operate by closely monitoring use of the new medicines involved, by recording all adverse drug reactions (however unimportant they may appear), and by returning cards promptly to the Medical Assessor, Committee on Adverse Drug Reactions, P.O. Box 913, Dunedin. Reporting cards, which will be identical to those available for the routine reporting of adverse drug reactions, will be included in the New Ethicals Catalogue, and will also be distributed by medical representatives of the manufacturing firms involved.

Only those new medicines selected on the recommendation of the Drug Assessment Advisory Committee will be included in the scheme and it is anticipated that a high reporting rate will be possible for this small group.

The medicines involved at the commencement of the scheme are:

Acebutolol hydrochloride (Sectral).
Atenolol (Tenormin).
Metoprolol tartrate (Betaloc, Lopresor).
Sotalol hydrochloride (Sotacor).
Perhexilene maleate (Pexid).
Sodium valproate (Epilim).

Any changes in this list will be notified in future Clinical Services Letters.

Reports returned to Professor McQueen will be collated and assessed by him so that the confidentiality of all information will be retained. Summaries of this information will be forwarded to the Department of Health and will also be assessed by the Drug Assessment Advisory Committee who will recommend any subsequent action.

The success of the scheme, which is similar to action being contemplated in other countries, will depend on a high level of reporting by individual practitioners. New Zealand is particularly suitable for such monitoring and is already gaining a reputation for its responsible reporting of adverse drug reactions. Earlier availability in this country of some new medicines may be possible as a result.

It is emphasised that reporting of adverse drug reactions which may be encountered from the use of other medicines should be continued in the normal manner.

Cyproterone Acetate (Androcur)

Cyproterone acetate is a potent hormone preparation with anti-androgenic action which has been released for marketing in New Zealand but only for the treatment of hypersexuality in adult males. On the recommendation of the Drug Assessment Advisory Committee, its use and distribution was restricted at first to psychiatrists only, but now includes other appropriate specialists.

The committee has been concerned about the use of this preparation for indications other than those for which consent to market has been approved. There has been some evidence in overseas literature of use for precocious puberty and hirsutism; this evidence will be further reviewed. At this stage, however, the Committee has not considered that there is sufficient satisfactory experience in these conditions to allay fears about the safe use of cyproterone acetate.

Accordingly, applications for free supply of Androcur as a supplementary pharmaceutical benefit will only be accepted from appropriate specialists for the treatment of hypersexuality in adult males. It is emphasised that this is potent therapy which should only be used after responsible assessment. Ethical implications must also be considered.

Attention is also drawn to recent reports of adrenal suppression following the use of cyproterone acetate.

Sodium Valproate (Epilim)

This medicine. which is recommended for the treatment of generalised, focal, or other epilepsy, received consent to market in New Zealand in August 1975. On the recommendation of the Drug Assessment Advisory Committee, distribution was restricted to appropriate specialists. This restriction was based on the desire for further long-term clinical data and in particular, the possible dangers of a link between sodium valproate and teratogenicity in humans.

Recently the necessity for this restriction has been reconsidered by the Drug Assessment Advisory Committee. Reports of platelet dysfunction, particularly with higher dosage, have now appeared in the literature, and the committee continues to be of the opinion that this medicine should be restricted to specialist use until further experience clarifies the situation.

For these reasons, applications for Epilim to be supplied free as a supplementary pharmaceutical benefit are only accepted when the application is made personally by an appropriate specialist. It is expected that specialists making such applications will keep the patient's general practitioner fully informed of the therapy prescribed, the nature of any side effects which might occur, and the action to be taken in such an event. Periodic specialist review would appear appropriate at this stage.

Gentamicin

Attention is drawn to the increasing problem of potentially lethal Gram-negative infections caused by gentamicin resistant organisms.

There is evidence that some of this resistance may arise within hospitals as a result of such factors as underdosing, proplylactic use, oral usage, and improper hygiene.

Nevertheless, the widespread usage of gentamicin in the community as a skin antibacterial agent remains a potential source of resistant organisms. Practitioners are requested to exercise restraint in their use of gentamicin for this purpose.

Payment of Benefits

It appears that it is not generally appreciated that provision exists for the payment of cheques for health benefits direct to a claimant's bank account.

Doctors wishing to avail themselves of this service should request the appropriate bank authority (Form Ty. 48) from their local district health office.

D. A. Andrews. A. G. Scott.

(D. A. Andrews)
Director,

(A. G. Scott)
Deputy Director,

Division of Clinical Services.

Vacancy at Queen Mary Hospital, Hanmer Springs

There will shortly be a vacancy for a Medical Officer of Special Scale at this hospital, which offers a stimulating treatment programme in the area of alcoholism. The position would suit somebody interested in developing group and individual psychotherapy skills, and there are opportunities for research. A younger doctor contemplating moving into general practice would find the position very worthwhile. For further details—contact the Medical Superintendent.

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