

# COMMITTEE ON SAFETY OF DRUGS

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LONDON S.W.1

Telephone: TRAFALGAR 6121

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Dear Doctor,

As Chairman of the Committee on Safety of Drugs I am writing to every member of the medical profession in the United Kingdom to ask for help. We ask you to report to us promptly details of any untoward condition in a patient which *might* be the result of drug treatment. We will also from time to time seek your co-operation in our research into adverse reactions by asking you to give us information concerning the health of patients who are receiving or have received drugs about which suspicions of serious side effects have been aroused.

## REPORTING ADVERSE REACTIONS: THE EARLY WARNING SYSTEM

The Committee is establishing a Register of Adverse Reactions to Drugs. If adverse reactions are promptly and accurately reported to us it will be possible for us to issue warning to doctors if we find that the frequency or seriousness of reactions to any particular drug constitutes a hazard to patients. Special business reply post cards have been printed for these reports and a supply is enclosed.

This early warning system depends for its success on the reports from doctors and for this reason the form has been kept brief so that you can complete it without delay. We ask you to give us the name of the patient concerned so that we can link up reports which may come to us both from the family doctor and a hospital doctor about a reaction experienced by the same patient. It will sometimes be necessary for our Medical Assessor to ask you for further information and if he does he will send a business reply addressed envelope for your reply.

## FURTHER RESEARCH INTO ADVERSE REACTIONS

In order to estimate the seriousness of reported adverse reactions it will be necessary for the Committee to find out how frequently reactions are occurring in relation to the number of times the drug is prescribed. The reports of adverse reactions sent to the Sub-Committee in accordance with the early warning system cannot give us this information with any degree of accuracy since to a doctor looking at cases in isolation it may not be obvious that an effect has an association with a drug. We can only determine the real ratio of adverse reactions to prescriptions by asking a number of doctors who have prescribed the drug about their experience in its use. We intend to take a sample of prescriptions written both by family doctors and by hospital doctors throughout the United Kingdom and then write to each doctor concerned asking him if he has noticed any particular untoward effects during or after treatment of the patients. Brief forms for reply and prepaid addressed envelopes will be sent with any enquiries which we hope will not be frequent.

## THE SPECIAL CONTRIBUTION OF GENERAL PRACTITIONERS IN NORTHERN IRELAND

I wish particularly to ask for the help of general practitioners in Northern Ireland. This is at present the only place in the United Kingdom, and probably in the world, where it is possible to find out accurately for a known population, the incidence of side effects when a drug is prescribed in general practice. This is because the Northern Ireland General Health Services Board has for many years used mechanical methods of coding and tabulating details of prescriptions, which have as yet no counterpart elsewhere. The Committee on Safety of Drugs has been offered co-operation by the Northern Ireland Ministry of Health and Local Government and the General Health Services Board in the use of this machinery for its work. It will be possible to trace rapidly

all prescriptions issued by general practitioners concerned might have been due to the drug. The general practitioner research will

relate to a given drug and then to see if it has or has not had any ill effects that in this new and important form of Committee.

#### CONFIDENTIAL NATURE OF ALL INFORMATION

All the reports or replies that the Committee receive from doctors will be treated with complete professional confidence by the Committee and their staff. The Health Ministers have given an undertaking that the information supplied will never be used for disciplinary purposes or for enquiries about prescribing costs.

#### THE IMPORTANCE OF THESE REPORTS

We appreciate that the reporting of adverse reactions and replying to our enquiries is an added burden for members of your profession and we shall restrict our enquiries to the minimum necessary for ensuring the safety of drugs. We are confident that you will give us your co-operation in this matter, for this is the only way by which knowledge of the presence and prevalence of adverse reactions to drugs can be obtained. Sometimes it may become clear that a drug should only be used with great caution, but equally important, we may be able to obtain evidence that anxieties about a useful drug are unfounded. Only with the help of all doctors will it be possible for us to keep the profession promptly and accurately informed about such matters which are of great consequence to the health of patients.

Yours sincerely,