Report of the Expert Group
on the Establishment of a

PROTOCOL

for the

PRESCRIBING OF METHADONE

March 1993

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DEPARTMENT
OF HEALTH
AN ROINN
SLAINTE

1

Introduction

1.1 Of the 315 cases of AIDS reported in this country, (to 25 February, 1993), 144 were drug use related; 1,381 persons had tested positive for the HIV antibody in the same period and almost 50% of these cases were drug use related. It is therefore apparent that injecting drug use is extremely high risk behaviour and an important source of transmission of the HIV virus in this country, Methadone therapy together with counselling and needle exchange are recognised strategies in preventing the spread of the HIV virus.

However, the use of methadone presents problems for patients, pharmacists, doctors and health workers. This Group has addressed these difficulties in order to develop a practical protocol that will ensure maximum benefit for the patient while at the same time protecting the pharmacists, doctors and health workers involved in methadone therapy in the community.

1.2 The National AIDS Strategy Committee has accepted the recommendations of the four sub-committees which it had previously established to examine various aspects of its brief. The Strategy Committee endorsed the recommendation that it would be necessary to allow methadone prescribing in the proposed satellite clinics in order to ensure that drug users availed of the full range of treatment services. It was also accepted that agreed protocols for the treatment of drug-using individuals needed to be established in order to avoid unnecessary pressure being placed on the general practitioner to prescribe opiates and other drugs. It was envisaged that this would also lead to the avoidance of double prescribing and inappropriate prescribing. The National AIDS Strategy Committee considered that the appropriate agencies to prepare such protocols were the Drug Treatment Centre, the Eastern Health Board, the Irish College of General Practitioners and voluntary drug agencies.

INTRODUCTION

1.3 Accordingly, the Minister for Health established an Expert Group with the following membership to develop the protocol:

Dr J. H. Walsh, Department of Health *(Chairman)*
Dr. J. Barry, Drugs - HIV/AIDS Co-Ordinator,
Eastern Health Board;
Mr. T. Geoghegan. Project Leader, Merchant's Quay Project;
Dr. J. O' Connor, Clinical Director, Drug Treatment Centre;
Dr. F. O' Kelly, Irish College of General Practitioners;
Dr. B. Sweeney, Consultant Psychiatrist,
Eastern Health Board, Psychiatric Services;
Mr. D. Ryan, Department of Health,
was appointed Secretary to the Group.

1.4 The Group were asked to consider the following in particular:

- methadone prescribing
- registration of drugs users and
- licensing of general practitioners to treat drug users,

1.5 The Group gratefully acknowledges the submissions received from individuals and organisations which greatly assisted the Group in the preparation of this report. In particular the supportive and cooperative assistance offered by the Pharmaceutical Society of Ireland and the Irish Pharmaceutical Union was essential to the preparation of this report. The Group is also most appreciative of the work and support of the Irish College of General Practitioners in the areas of illicit drug use and drug addiction.

1.6 The Group wishes to record its acknowledgement of the valuable contributions to the work of the Group made by Ms. S. Stafford Johnson, Senior Clinical Psychologist and Dr. E. Keenan, Senior Registrar, both of the Drug Treatment Centre.

2

Community Based Treatment of Drug Users

2.1 Methadone prescribing

The National AIDS Strategy Committee accepted that the prescribing of methadone was necessary to ensure that drug users would be encouraged to avail of the full spectrum of preventative measures and treatment services. This is particularly significant in view of the preponderance of HIV/AIDS in the drug-using community resulting in the spread of the infection as a result of sharing of contaminated needles. The Group discussed its remit at some considerable length and finally agreed on the following basic tenets:-

(i) That maintenance programmes represented, for many users, their most feasible option for stablising their addiction. These programmes had obvious attractions for service users.

(ii) Methadone prescribing is important to ensure
   (a) that the maximum number of users avail of treatment services;
   (b) the prevention of transmission of the HIV virus through infected needles.

(iii) That methadone is the most appropriate drug for use in a maintenance programme for addiction. The Group holds this view so strongly that it would specifically list the following drugs as being unsuitable for such programmes:
   Morphine (MST); Dihydrocodeine (DF118);
   Buphrenorphine (Temgesic); Dipipanone (Diconal);
   Dextromoramide (Palfium).

The Group is aware that benzodiazepines have potential for abuse and some of them (e.g. Flunitrazepam (Rohypnol) and Temazepam (Normison)) are being injected thus perhaps contributing to the transmission of HIV. The Group recognises that benzodiazepines are useful in the short term treatment of anxiety and insomnia but stress that prescribing doctors should be aware of the abuse associated with them.

2.2 Methadone, like any other addictive drug, is liable to abuse from a number of sources. Therefore, a number of safeguards must be introduced to avoid problems caused by double prescribing and its subsequent availability on the black market. Consequently it was agreed that control of methadone prescribing was essential. This allows the following advantages:

(a) the protection of the service and its users

(b) the protection of the service providers

(c) an aid to appropriate and responsible prescribing

2.3 The Group recognised the validity of Dr. John O' Connor's guidelines entitled: *Good Clinical Practice in Relation to Methadone Prescribing* as a basis for clinical practice. Dr. O' Connor's paper is reproduced at Appendix A.

2.4 In recognition of the complexities of the medical and psycho-social issues involved in the treatment of drug use the Group considered that the importance of a multidisciplinary approach should be emphasised. The Group considered that a "team approach" to the admission of a patient to a methadone prescribing regime was most important. This issue is expanded upon later in this report.

3

The Role of the General Practitioner in Community Methadone Maintenance Programmes

3.1 The Irish College of General Practitioners has stated in its *Policy Statement on illicit Drug Use and Problems of Drug Addiction* that the College supports the provision of community drug teams and that these teams should work closely with local general practitioners. Doctors who wish to prescribe for patients with addiction problems should do so only when satisfied about the adequacy of support from the statutory and voluntary services and the availability of proper resources. The Group endorses this view and would stress that such prescribing should be within the guidelines issued by the Medical Council for the prescribing of controlled drugs. (The Medical Council Guidelines are at Appendix B).

3.2 In practice it is recommended that a person in difficulty with his/her drug use should be referred either to the Drug Treatment Centre or to the local health board addiction services or to the local community drug team for a full assessment, including a psychiatric evaluation. The initial referral could be from the individual's own doctor, public health nurse, drugs out-reach worker, voluntary agency or by self-referral. Following assessment it is recommended that the individual should be offered a range of options including detoxification, support for a drug-free life, referral to a programme of rehabilitation, or a methadone maintenance programme. A key drug worker would be identified to work with this person on an on-going basis. After stabilisation as drug-free or on a maintenance programme the individual would be introduced to a local doctor who had agreed to continue medical care and/or methadone maintenance at a level agreed between the doctor, the patient and the addiction services. The Group endorses the role of the community drug team and recommends the urgent establishment of other community drug teams in areas of greatest need.

3.3 There should be regular communication between the doctor and the addiction services through the patient's key drug worker. This should ensure that any problems which arise concerning the

treatment are quickly identified and dealt with at the most appropriate level. This would give support and protection to the patient, the doctor and the addiction services. The Group therefore recommends that close co-operation should exist between general practitioners and the community drug team/addiction services for their area.

This would also have the effect of establishing the practice of "good care" in the prescribing of methadone to opiate-addicted individuals. All doctors would be encouraged to accept that this was the preferred treatment option for these problems.

General practitioners using such a system of care would work in cooperation with their local pharmacy colleagues, A nominated pharmacist would dispense for each individual drug user on a treatment or maintenance programme and therefore the role of the pharmacist will be essential in the on-going development of community drug teams.

3.4 It is considered that general practitioner sessions would initially take place in the community based (satellite) clinics but ultimately it is envisaged that the scheme would develop to the point where participating general practitioners would see patients in their own surgeries.

3.5 In providing this service the general practitioner would be strongly supported by the appropriate addiction service and by the community care services of the health boards. Liaison with acute and chronic hospital services dealing with HIV/AIDS cases will need to be fully developed to ensure that the service is as integrated and efficient as possible.

3.6 The Group recognises that there are general practitioners who are already prescribing methadone for patients in the community. As previously stated there are considerable difficulties for all concerned if doctors treat patients in isolation. Accordingly it is recommended that such doctors should contact the Drug Treatment Centre or the health board addiction services in order that their patients can avail of the full range of services available and to ensure

patients can avail of the full range of services available and to ensure that their own service is supported and protected (i.e. against the possibility of double-prescribing etc.).

3.7 The Group regards the support of the Drug Treatment Centre and of the health board addiction services as being vital to any methadone maintenance programme and would therefore recommend in the strongest possible terms that general practitioners should not become involved in the provision of such services unless they are provided in co-operation with the Centre and /or the addiction services.

3.8 It is important that all statutory and voluntary bodies working in the area of drug use and HIV/AIDS have good communications and work closely together to ensure maximum cooperation in order that an optimal level of services are provided to drug users and their families. This would serve to help them as individuals and also to prevent the spread of HIV infection which is associated with the identified drug use problem concentrated in certain areas of Dublin City.

4

Registration of Drug Users

4.1 Registration of drug users

The Group regarded the issue of the registration of drug users as crucial and were cognisant of the need to reach agreement on a formula which would be generally acceptable to all the relevant parties. It was agreed that there was widespread resistance to the term ‘register’ and accordingly it was decided that the use of the term ‘register’ was unnecessary and unwelcome.

However, it was agreed that a basic level of control had to be introduced in order:

(a) to protect the service

(b) to protect service users;

(c) to protect the service providers

(d) to avoid double prescribing

4.2 Treatment Card

Having regard to the fact that the Group was established to give effect to proposals that services should, as far as possible, be decentralised or community-based it was agreed that if a common method of entry to the community-based treatment/addiction services could be agreed then the above-mentioned objectives could be achieved. In recognition of the fact that there might be a certain hesitancy and anxiety concerning the provision of services to drug users at local community level, it was agreed that a treatment card should be introduced to help allay some of these fears. It was decided that a treatment card should be provided for each patient who is admitted to the detoxification/maintenance programmes in the community. Following the initial assessment and period of stabilisation a patient may be issued with a treatment card and referred to an agreed local general practitioner and pharmacist.

The card would remain the property of the patient at all times. The creation of a treatment card for a particular individual would be the outcome of a consultative process emphasising the benefits accruing

to both the service user and to the service provider. One of the obvious benefits would be that it would facilitate integration into the community and therefore the provision of such a card for each treatment user would be desirable and welcomed by both service users and providers.

It is recommended that the following should be included on the treatment card:

the name of the patient

the date of birth of the patient

a photograph of the patient

the name of the prescribing doctor

It is also recommended that the card should be deposited with the pharmacist or appropriate dispensing service by the patient for the duration of his/her treatment programme,

Acceptance of the card by the pharmacist would not of itself permanently bind him/her to provide services for a particular patient. Likewise the patient could withdraw the card, for example on termination of his/her treatment programme. In order to avoid as far as possible future problems of stolen or mislaid cards and to allay any unwarranted concerns regarding confidentiality, it is recommended that each card should be valid for a specific period and should carry an expiry date after which a new card would be required for continuation of treatment. It is recommended that the cards should issue from two sources only; the Drug Treatment Centre, and the health board addiction services.

4.3 Treatment list of service users

In tandem with the proposed treatment card the Group agreed that there was a clear need for a list of patients to be maintained centrally not least for purposes of assessing both current levels of service provision, and of future trends. Having regard to all the circumstances it was agreed that the Drug Treatment Centre (Trinity Court), would be the preferred centre where such a list should be maintained. This would have a number of advantages including the most obvious that there would be a central resource which would have basic identifying details of all patients seeking treatment throughout the country. The proposed list would include details such as the patient’s name and date of birth. A patient’s name will be deleted from the list after an appropriate period out of treatment,

usually one year.

It is recommended that for the purposes of co-ordination, each health board providing a service such as has been described, should designate a doctor to form a Liaison Group with the Clinical Director (or his deputy) of the Drug Treatment Centre for the purposes of ensuring the protection of users/providers, the services and the avoidance of double prescribing.

The Group wishes to place particular emphasis on two issues in this general area:

(a) *Confidentiality:* in this regard it is recommended that because of the nature of the information, access to the list should be restricted to doctors providing treatment. The maintenance of the list will, of course, comply with the provisions of the Data Protection Act, 1988. In accordance with the provisions of the Act, individuals who believe that information is being maintained on computer will be able to apply for disclosure of such information in accordance with the usual procedures.

(b) *Liaison and Co-operation:* the Group wish to stress the need for a high level of liaison and co-ordination between the designated doctors who will have responsibility for the maintenance/operation of the list.

Unlinked statistics will, of course, be available to the Department of Health, and other interested agencies.

In order to avoid any undue pressure being put on the designated doctors to release information, the Group wish to stress that the list is a treatment list, and is not to be anything other than such a list. The Group would also wish to emphasise that where information is sought regarding a particular individual it should be sought from the initial referring doctor.

4.4 Dispensing of Methadone

The Group met with the Irish Pharmaceutical Union (ECU) and the Pharmaceutical Society of Ireland (PSI). The Group was most encouraged by the positive response of both organisations and their willingness to encourage their members to support the proposed initiatives. In practice it was agreed that the community-based

pharmacist would only dispense methadone to an individual for whom he/she held a treatment card. The prescription issued by the doctor would be marked "To be dispensed in ---------- pharmacy only" which would be an additional safeguard against double prescribing. It was agreed that the particular time of delivery and collection of prescriptions by users should be agreed locally in order to minimise disruptions to the other activities of the pharmacy and to enable the pharmacist to order methadone as it was required rather than to force the retention of excessive quantities in stock. The Group were strongly of the view that methadone should be dispensed in the same manner as any other similar medication. Individuals should not be forced to consume the methadone on the premises.

4.5 The Group were aware that some drug users may not have access to dispensing community pharmacies. In such cases the Group recognises the validity of centralised arrangements for the dispensing of methadone.

5

Licensing of General Practitioners to treat Drug Users

5.1 The Group recognised that this was a very contentious area not least because of the difficulty of involving general practitioners in the treatment of drug users. The National AIDS Strategy Committee had envisaged that with the provision of adequate facilities and safeguards general practitioners would be prepared to take on a comprehensive role in the care and treatment of drug users. The Group, however, was of the view that licensing would be perceived as very much a negative step and would be opposed by the doctors and their representative organisations. It might, therefore, discourage general practitioners from becoming involved in the provision of services.

5.2 The Group considered that the need for such a form of control would be partially obviated by the introduction of the treatment card, as recommended earlier in this Report. The introduction of guidelines for good practice will also assist in clearly defining the role of the general practitioner in the treatment of drug users. As previously stated in Paragraph 3.3 the Group strongly recommend that the prescribing of methadone should only take place within the context of a recognised treatment programme with active support from the various addiction services, statutory or voluntary, and following the guidelines recommended by this Group.

5.3 The Group did recognise the value of registration of general practitioners as a positive measure rather than as a means of imposing restrictions or control. A scheme, similar to the combined ante-natal care scheme was suggested, whereby doctors would contract to provide care under agreed conditions and for agreed remuneration. Any doctor would be eligible to apply to participate in the scheme to the appropriate health board. The doctor would keep a list of consultations which would be forwarded for review by the appropriate medical officer and passed for payment in due course.

6

General Issues

6.1 Co-ordination and co-operation

The Group are very aware that the recommendations which are contained in this report have wide-ranging implications for the delivery of services to drug users. The measures which are recommended will change existing services and offer clear guidelines for the delivery of new evolving services. The Group fully appreciates the difficulties that could arise in the implementation of the recommendations it has made and reiterates the need for the closest possible co-operation and liaison in the delivery of the services.

This Group is confident that the support and co-operation which has been promised by all concerned will help to avoid many difficulties which might otherwise occur. However, in order to ensure that any difficulties which do arise are dealt with as expeditiously as possible, in the operation of the protocol and in the implementation of the other recommendations contained in this Report, the Group recommends that it should continue in existence for an initial phase-in period of twelve months in order to monitor and evaluate the proposed arrangements. At the end of this period the situation and necessity for such a Group should be reviewed.

6.2 The following are areas of concern which the Group believe should be monitored for an initial period:

(i) co-operation and liaison between the various addiction services both statutory and voluntary;

(ii) co-operation and liaison between the doctors designated by the Drug Treatment Centre and the health board addiction services in the operation of the treatment list.

(iii) the avoidance of double prescribing and inappropriate prescribing by the implementation of the Group's recommendations and, in particular, the operation of the proposed treatment card.

7

Summary of Recommendations

(i) It is recommended that methadone is the most appropriate drug for use in a maintenance programme

(ii) It is recommended that doctors who wish to prescribe for patients with addiction problems should do so only when satisfied that they are complying with the Medical Council guidelines on the prescribing of controlled drugs and where there is satisfactory support from the statutory and voluntary

(iii) It is recommended that before a person is admitted to a maintenance programme he/she should be referred either to the Drug Treatment Centre or to the local health board addiction services or to the local community drug team for a full assessment including psychiatric evaluation.

(iv) It is recommended that, following assessment, the individual should be offered a range of options including detoxification, support for a drug-free life, referral to a programme of rehabilitation, or a methadone maintenance programme.

(v) The group recommends the urgent establishment of other community drug teams in areas of greatest need.

(vi) The Group recommends that close co-operation should exist between general practitioners and the community drug team for their area.

(vii) It is recommended that doctors who are currently treating patients with methadone should contact the Drug Treatment Centre or the health board addiction services in order that their patients can avail of the full range of available services and to ensure that their own service is supported and protected.

(viii) It is recommended that a **treatment card** should be provided for each patient who is admitted to detoxification/maintenance programmes in the community and that each card should be valid for a specific period.

(ix) It is recommended that the card should issue from two sources only; the Drug Treatment Centre and the health .....board addiction services.

(x) It is recommended that a list of all patients on methadone therapy should be maintained and operated by a liaison group consisting of a designated doctor from each health board addiction service and the Clinical Director (or his deputy) of the Drug Treatment Centre.

(xi) It is recommended that because of the confidential nature of the information, access to the list should be restricted to doctors providing treatment and comply with the guidelines set out by the Medical Council and the Data Protection Act.

(xii) It is recommended that community-based pharmacists should only dispense methadone for individuals for whom they hold a treatment card and that methadone should be dispensed in the same manner as any other similar medication.

(xiii) It is strongly recommended that the prescribing of methadone should only take place within the context of a recognised treatment/maintenance programme encompassing support from the various addiction services, statutory or voluntary, and following the guidelines recommended by this Group.

(xiv) It is recommended that the Group should continue to monitor and evaluate the proposed arrangements and their operation for an initial phase-in period until the measures recommended in this report are operating satisfactorily.

APPENDIX A

Good Clinical Practice in Relation to Methadone Prescribing

Dr. John J. O' Connor
Consultant Psychiatrist/Clinical Director

January 1993

THE DRUG TREATMENT CENTRE BOARD
Trinity Court
30/31 Pearse Street Dublin 2

Telephone 677 1122

Methadone has a similar pharmacological spectrum to heroin. It is usually taken orally and in view of its longer half-life can be given on a once daily dosage thus ruling out the need to inject drugs and the drug-seeking behaviour, that ensues.

MEDICAL: Medical examination should include assessment of respiratory, cardiac, G.I.T. and C.N.S. systems. The medical evaluation should also include examination of a patient's upper and lower limbs and groin i.e. injection sites.

PSYCHIATRIC: Psychiatric evaluation includes examination for any co-existing personality disorder, mild mental handicap, psychotic or depressive illness,

SOCIAL: Social history should be obtained at this stage and where possible a collateral history from a relative or concerned person.

URINALYSIS: Obtaining urine should be supervised and analysis carried out for the following reasons:

(a) urine checked for particular drugs of abuse, and that the results are consistent with the patient's history;

(b) to ensure that the patient is not already receiving methadone elsewhere.

TREATMENT PLAN: Methadone Detoxification/Maintenance

The decision as to whether a patient should be given a detoxification or maintenance is based on a number of factors. It is good clinical practice to encourage a patient on first presentation to become drug free and avail of the opportunity for an independent lifestyle. Maintenance is usually decided as the best option if:

(a) previous failed detoxifications

(b) inability to remain drug free

(c) length of time abusing drugs

(d) physical ill health: medical problems including HIV

(e) in the case of women - pregnancy

For a withdrawal regime a starting dose on 30-40 mgs ought to be sufficient, and thereafter reducing by 5 mgs every three days. It should be remembered that psychological factors play a large part in the manifestations of the withdrawal syndrome and a supportive reassuring approach can often greatly reduce the severity of the symptoms experienced.

Many patients are not as physically dependent on opiates as they assume, particularly if they have been using heroin which can be very impure. Dublin street heroin is on average only 10 - 15 % pure. It is better to prescribe a lower dose and then increase it if the person is experiencing withdrawal symptoms than to prescribe a level that will induce intoxication and increase physical tolerance. Methadone should initially be administered on a daily basis and evidence of improvement in drug taking behaviour should include reference to regular supervised urinalysis. A few days supply of methadone should only be given to those who cope well with daily administration.

A patient presenting in obvious withdrawals can either be given symptomatic relief with melleril, ponstan and lomotil or a low dose of methadone followed by referral the next day to a treatment centre.

ABUSE POTENTIAL: The potential for abuse of methadone should not be forgotten. Already there is a thriving black market for methadone on the street. To combat this and the problem of double scripting it is essential, that a central register for methadone prescribing be instituted immediately.

Finally, methadone should not be seen as an easy solution to a complex problem. Methadone should always be regarded only as an adjunct to treatment and not treatment per se.

APPENDIX B

RECOMMENDATIONS

OF THE MEDICALCOUNCIL FOR THE PRESCRIBING OF CONTROLLED DRUGS UNDER THE MISUSE OF DRUGS ACT, 1977

1 Practitioners must ensure that all prescriptions for controlled drugs are written in the format specified in the Misuse of Drugs Regulations. Incorrectly written prescriptions cannot lawfully be dispensed by pharmacists.

2 Practitioners and pharmacists in each area should reach an understanding about prescribing and dispensing controlled drugs. On the basis of such understanding pharmacists should be in a position to meet the legitimate needs of patients promptly.

3 Practitioners should not treat patients from outside their practice areas for addiction problems by prescribing controlled drugs. Practitioners are advised to refer such patients to recognised drug treatment centres.

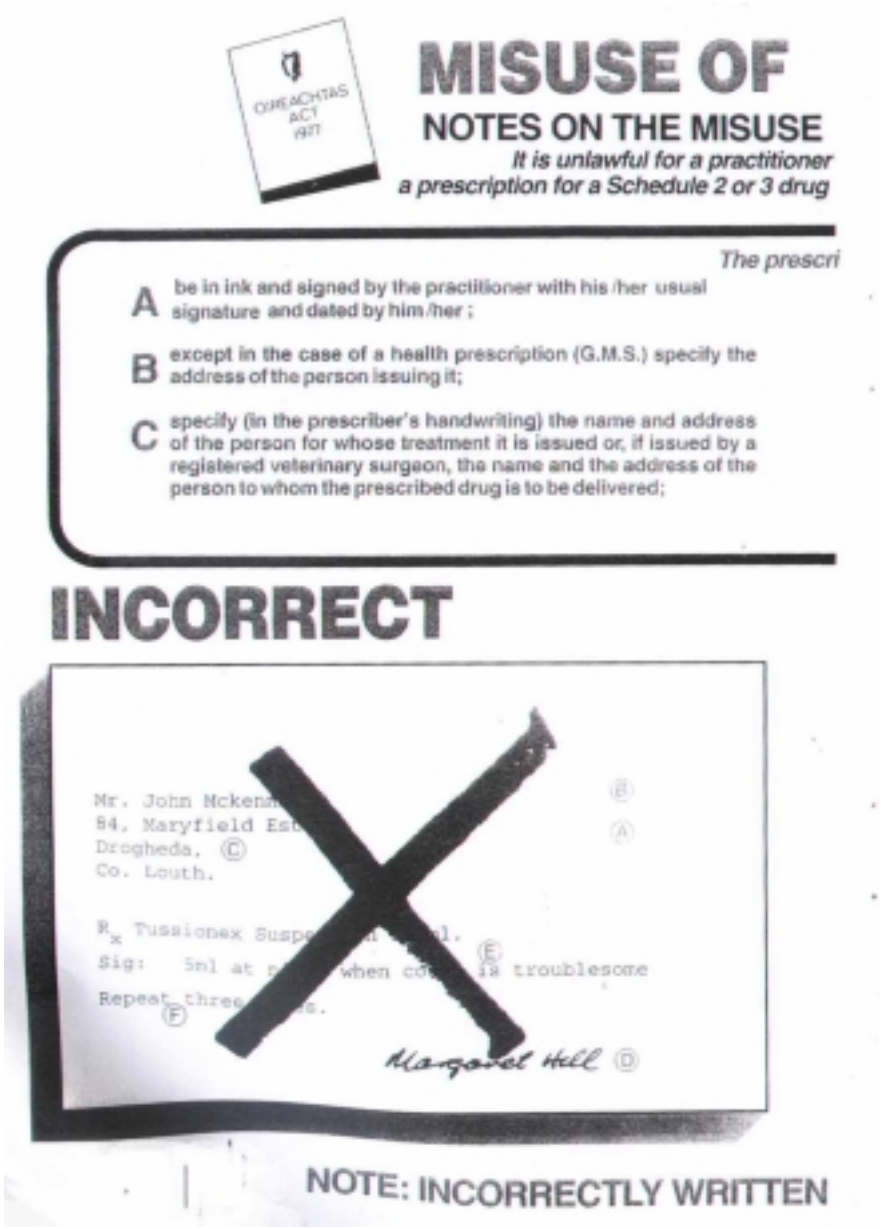
4 Patients should be discouraged from moving from pharmacy to pharmacy with prescriptions for controlled drugs.

5 A practitioner who has patients referred from a drug treatment centre for continuation of treatment, with the patient's consent, should discuss the likely treatment regimen with the patient's pharmacist.

6 Doctors should report problems in the prescribing of controlled drugs to the Medical Council.

AN ROINN SLAINTE
Department of Health

Issued on behalf of the Medical Council and the Pharmaceutical Society of Ireland. Japan 1987


OIREACHTAS
ACT
1977
MISUSE OF
NOTES ON THE MISUSE
It is unlawful for a practitioner
a prescription for a Schedule 2 or 3 drug
The prescri
A be in ink and signed by the practitioner with his /her usual signature and dated by him /her ;
B except in the case of a health prescription (G.M.S.) specify the address of the person issuing it;
C specify (in the prescriber's handwriting) the name and address of the person for whose treatment it is issued or, if issued by a registered veterinary surgeon, the name and the address of the person to whom the prescribed drug is to be delivered;
INCORRECT
Mr. John Mcken
84, Maryfield Est
Drogheda. C
Co. Louth.
Rx Tussionex Susp
Sig: 5ml at
when co
is troublesome
Repeat three
F
Margaret Hill D
B
A
E
NOTE: INCORRECTLY WRITTEN

DRUGS ACT 1977

OF DRUGS REGULATIONS 1979

to issue, or for a pharmacist to dispense,
unless it complies with the following requirements.

ption must

D state whether the person issuing it is a registered medical practitioner, registered dentist or registered veterinary surgeon;

E specify (in the prescriber's handwriting) (i) the *dose* to be taken, (ii) the *form* in the case of preparations, (iii) the *strength* (when appropriate) and (iv) in both words and figures, either the *total quantity* of the drug or preparation or the *number of dosage units* to be supplied.;

F in the case of a prescription for a total quantity intended to be dispensed by instalments, specify the quantity, the number of instalments, and the intervals to be observed when dispensing.

CORRECT

Mr John McKenna (C)
84 Marsfield Estate,
Drogheda.
Co Louth.

(B) Ardnaree
Collon
Co. Louth

1 Nov. 1985 (A)

℞ Tussionex Suspension
Mitte 100 (one hundred (E)(iv) sixty five) ml
Sig: (E)(i) at night when cough is troublesome
Supply in three instal ments of 55 ml (F)
at intervals of three weeks (F)

(A) Margaret Hall M.D. (D)

PRESCRIPTIONS ARE ILLEGAL.