
Review of the
METHADONE TREATMENT
Protocol



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REVIEW OF THE METHADONE TREATMENT PROTOCOL

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1. INTRODUCTION

In January 1998 the report of the Methadone Treatment Services Review Group was published.

The Methadone Treatment Services Review Group had been set up by the Department of Health and Children in 1997 to assess the use of methadone in the treatment of heroin dependence. The Review Group included representation from the then Eastern Health Board, the Department of Health and Children, the Irish College of General Practitioners, the Pharmaceutical Society of Ireland and a representative of the Consultant Psychiatrists working in substance abuse.

Its report examined the protocols for good practice in the prescribing and dispensing of methadone and pointed to appropriate controls that could be put in place. It also set out the basis on which methadone treatment should continue to be developed and recommended a concise framework for the future operation of the Scheme. The report was circulated nationwide to every general practitioner and pharmacist.

An implementation committee, comprising representatives from the then Eastern Regional Health Authority, the seven health boards outside the eastern region, General Medical Services (Payments) Board, the Irish College of General Practitioners, the Pharmaceutical Society of Ireland and the Department of Health and Children was established with responsibility for implementing the recommendations contained in the report.

In 2002 the Department of Health and Children requested the Methadone Prescribing Implementation Committee to conduct a review of the Methadone Protocol that was introduced in October 1998. The membership of this committee is attached. (Appendix 1).

Other medicines, such as Lofexidine, Naloxone, Naltraxone and Buprenorphine are also used in the drug treatment setting but protocols for these treatments are not within in the remit of this committee and therefore do not form part of this review.

2. TERMS OF REFERENCE:

- To review the operation of the methadone protocol and its role in providing methadone treatment and rehabilitation of opiate users both in and outside the greater Dublin area
- To review the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998 (S.I. 225 of 1998) and the report of the Methadone Treatment Services Review Group (1997) in order to advise on their applicability and relevance nationally
- To review the role and working relationships within and between the Department of Health and Children, the Drug Treatment Centre Board, the health boards/ERHA, the Irish College of General Practitioners, the Irish College of Psychiatrists, the Pharmaceutical Society of Ireland, the Irish Prisons Service, general practitioners, pharmacists, community and voluntary groups and other agencies in the provision of methadone treatment
- To consult with relevant stakeholders
- To report and make recommendations as appropriate to the Department of Health and Children.

3. METHODOLOGY

It was decided that there would be a call for submissions to the committee from the public and that specific bodies involved in methadone treatment would be asked individually if they wished to make submissions. An advertisement was placed in the national newspapers stating that the committee was reviewing the Methadone Treatment Protocol and inviting submissions from interested members of the public and other interest groups. (Appendix 2).

The current structure of the Methadone Treatment Protocol and services was reviewed, including the expansion of client, GP and pharmacist service numbers since 1998.

The implementation of the recommendations of the Methadone Treatment Services Review Group was assessed. (Table 1).

The committee received 46 submissions from a number of sources including individual members of the public, community groups, NGOs, health boards, health professionals working in the field of drug misuse and their representative bodies. (Appendix 3).

The submissions were analysed by the committee and the recurrent themes identified. The review committee discussed the recurrent themes and recommendations are made on the basis of these discussions.

4. METHADONE REGULATIONS

The Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998 came into operation in July 1998.

These regulations state that: -

When a registered medical practitioner intends to prescribe a specified controlled drug to a person for the first time a prescription should not be issued until the medical practitioner notifies the Eastern Health Board of the name, address and date of birth of that person. The Eastern Health Board shall maintain a record (the Central Treatment List) containing this information, which may be maintained in electronic form. The Eastern Health Board may amend an entry in or delete an entry from this list. The Eastern Health Board shall inform the medical practitioner if the person is previously on the list.

A health board shall issue a drug treatment card for a person participating in the scheme after they have been notified to the Eastern Health Board (EHB). This card is valid for a maximum of one year from the date of issue. A medical practitioner shall only issue prescriptions for the specified controlled drug on the special forms supplied and only to a client with a valid treatment card.

A pharmacist can only supply the specified controlled drug on a specific prescription to a person who has a valid treatment card. The pharmacist must forward to the Department of Health the original prescription.

The Minister shall maintain a record of all prescriptions received by him, which may be kept in electronic form, and the Minister may amend or delete an entry. Each prescription should be kept for two years.

Exemptions: -

Hospitals: - The regulations shall not apply to prescriptions issued in respect of a specified controlled drug where the prescription has been issued in a hospital for administration or supply in the hospital to a person who attends the hospital for treatment of opiate dependence or who is an in-patient who is opiate dependent.

Medical Consultants: - the regulations do not apply to a prescription issued for the treatment of a person other than in connection with opiate dependence provided that the medical consultant's name and address is on the prescription and that the official prescription form is used.

It should be noted that best practice is that opiate dependent patients should not be treated in a hospital setting without appropriate contact with the addiction services.

5. CURRENT STRUCTURE

5.1. Background

Prior to the introduction of the Methadone Protocol in 1998 a situation existed whereby only a small number of GPs were prescribing methadone. This resulted in a large number of drug misusers travelling long distances to all parts of Dublin in search of methadone. This affected the communities in which these GPs practiced. Also at this time there was anecdotal evidence that a large quantity of methadone and physeptone was available for sale on the black market.

A system of close monitoring of all elements of the scheme was put in place on foot of the methadone regulations. The Methadone Protocol Implementation

Committee was set up to monitor the scheme and meets on a quarterly basis. The Methadone Treatment Services Review Group recommended and it has been established, that the Methadone Treatment Protocol be available nationally and that treatment for opiate misuse should be provided in the misuser's own local area whenever possible. Methadone treatment is now provided throughout the country by general practitioners. The Midland, South Eastern, Mid-Western and Western Health Boards (now the Health Service Executive) also established clinics.

Locally based methadone treatment for opiate misusers is provided through drug treatment clinics, satellite clinics or through general practitioners in the community.

5.2. Treatment Clinics

Currently there are 59 treatment locations in the Health Service Executive (HSE) Eastern Regional Area. These are a mix of larger addiction centres and satellite clinics. This is an increase of 47 locations since 1996. The Drug Treatment Centre Board an independent statutory service provides a tertiary service to meet the needs of the homeless population, those with a dual diagnosis or specialist medical needs. Six treatment clinics are located outside the HSE Eastern Regional Area (Figure 1). Some drug misusers attend the larger addiction centres where methadone is dispensed on site. Drug misusers can also receive treatment at satellite clinics where treatment is provided by a GP; methadone is prescribed at the clinic and then dispensed by a community pharmacist. Drug misusers attending satellite clinics are usually less chaotic than those attending the larger addiction centres. Drug misusers attending the larger addiction centres and the satellite clinics are all registered on the Central Treatment List. At the end of December 2003 there were 6,883 clients receiving methadone treatment, compared with 1,861 at the end of December 1996. (Figure 2).

Figure 1 The number of Treatment Clinics 1996 – 2003.

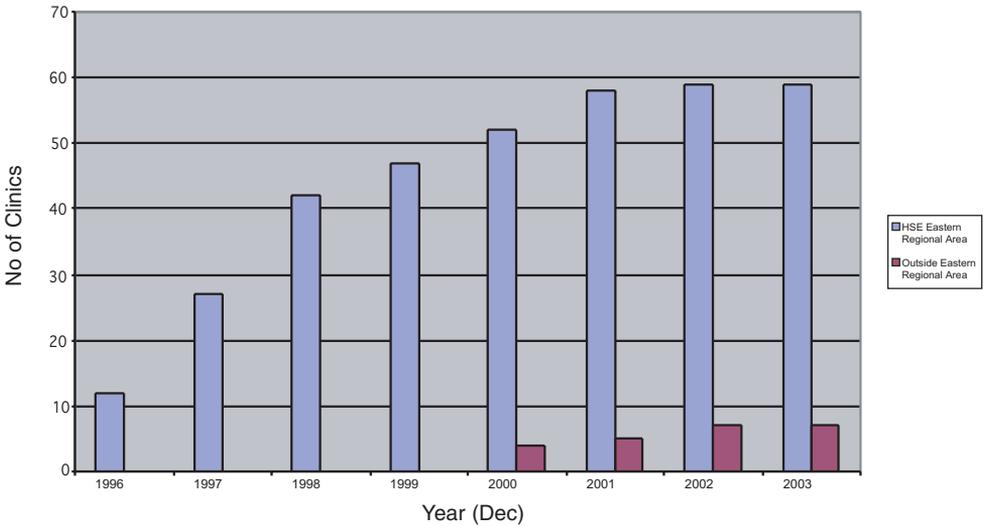
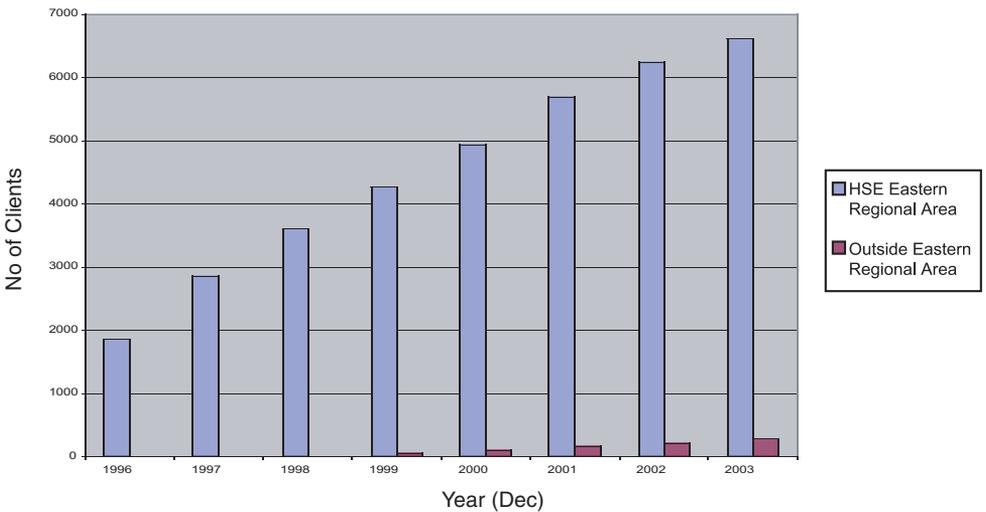


Figure 2 The number of Clients in Treatment 1996 - 2003



5.3. General Practitioners (GPs)

The Methadone Treatment Services Review Group recommended and endorsed the scheme of general practitioner involvement outlined in the Irish College of General Practitioners' report. Under the scheme general practitioners are contracted to provide treatment on the basis of one of two levels – Level 1 or Level 2. At the end of December 2003 there were 205 GPs involved in the Methadone Protocol compared with 56 in December 1996. (Figure 3).

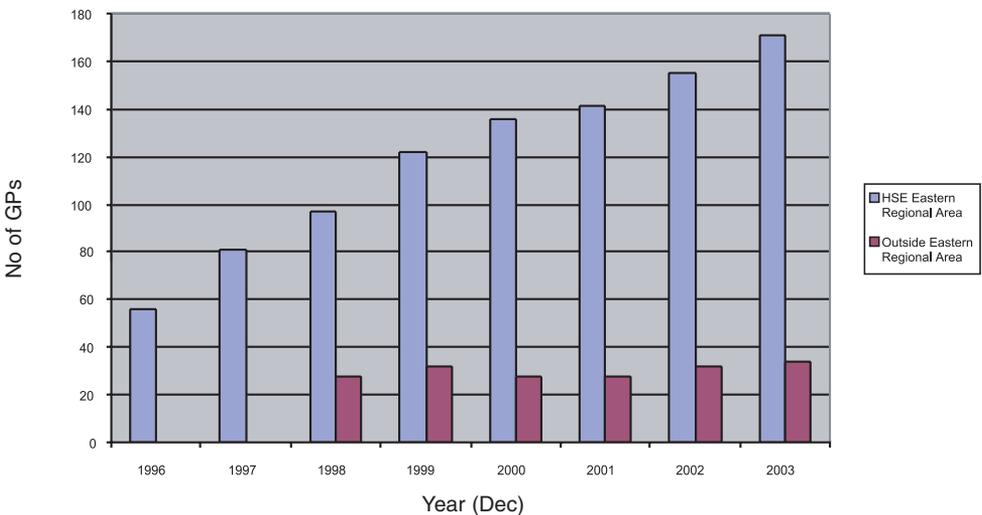
Level 1

- Level 1 GPs treat stabilised opiate dependent persons who have been referred from HSE drug treatment centres or from Level 2 GPs.
- To practice as a Level 1 GP s/he must complete a recognised training programme coordinated by the Irish College of General Practitioners and agree to regular educational updates.
- The GP is regularly evaluated/audited by the Irish College of General Practitioners.
- The person attending the GP is registered on the Central Treatment List and is issued with a treatment card, which is kept by a specified pharmacist.
- A Level 1 GP can treat up to a maximum of 15 patients.
- The GP receives no fees from the client or any other source except from the HSE for this service.
- The GP can only issue a prescription for a supply for a period of not greater than seven days.
- The prescriptions for methadone are subject to control under the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998.

Level 2

- This is a GP who has undergone more training than a Level 1 GP and who is more experienced in working with opiate dependent persons. These GPs can initiate treatment of opiate dependent persons.
- The Level 2 GPs have undergone a more advanced training programme agreed between the Irish College of General Practitioners and the HSE and includes 13 clinical sessions in a range of different clinical settings and is supervised by a designated GP mentor.
- The GP can treat up to maximum of 35 patients or a maximum of 50 in a partnership with 2 or more doctors in their own practice.

Figure 3 The number of GPs providing treatment 1996 – 2003.

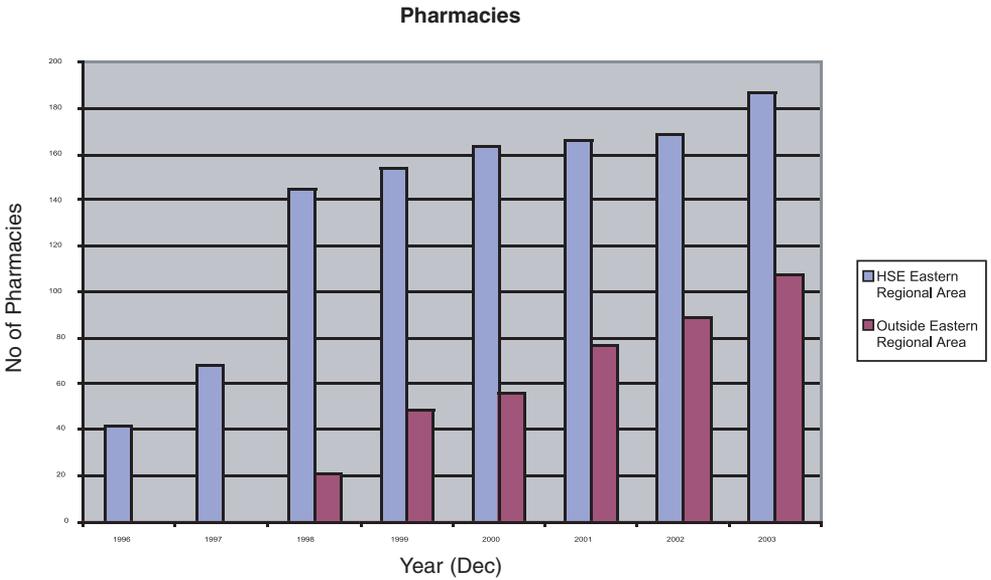


5.4. Role of the Pharmacist

The involvement of the community pharmacists in the dispensing of methadone allows for a large number of opiate dependent persons to be treated in their own local area as recommended by the Methadone Treatment Service Review Group. In December 2003 there were 295 community pharmacists involved in the Protocol compared with 42 in December 1996. (Figure 4).

- Under the Community Pharmacy Contractor Agreement the HSE can agree with individual pharmacies to dispense methadone mixture DTF1mg/ml to opiate dependent persons in their local areas on a special methadone prescription form.
- Methadone can only be dispensed to clients who hold a valid treatment card issued to them by the Central Treatment List. This card is held in the pharmacy for the duration of treatment or until it expires, is replaced or withdrawn.
- If a client fails to comply with an agreed code of behaviour then the client can be referred back to the HSE treatment services.
- The pharmacists are trained on how the system works by the GP co-ordinator or the liaison pharmacist (applies to HSE Eastern Regional Area only) and it is recommended that there are regular educational updates on drug misuse and specifically on methadone treatment.

Figure 4 The number of Pharmacies providing treatment 1996 – 2003



5.5. Progress on recommendations of Methadone Treatment Services Review Group Report

The following table outlines the progress on the recommendations made since the introduction of the Methadone Protocol.

SUMMARY OF MAIN RECOMMENDATIONS	RESPONSE TO RECOMMENDATIONS
Methadone treatment should continue to be a valid treatment for opiate dependence, as part of a comprehensive programme of care.	Considerable progress has been made in the range of drug treatment services available. However, further progress needs to be made in this area. The implementation of Action 48 of the National Drugs Strategy, which states that each health board area should have in place a range of treatment and rehabilitation options as part of a planned programme of progression, will respond to this.
The Protocol for the Prescribing of Methadone as set out in March 1993 should be the basis on which the further development of services for opiate dependent persons is undertaken, subject to appropriate controls.	This has been implemented.
There should be only one form of methadone used for the treatment of opiate dependence - methadone mixture DTF 1mg/ml. Methadone linctus 2mg/5ml should be discontinued, except on a "named-patient" basis.	This has been implemented.
The sugar free formulation of methadone mixture DTF 1mg/ml should be used, except in exceptional circumstances and bottles should be fitted with childproof caps.	This has been implemented.
Methadone should be available free of charge to all persons undergoing methadone treatment for opiate dependence.	This has been implemented.
The methadone treatment protocol should be available nationally.	This has been implemented.
The prescription and supply of methadone should be strictly controlled and a system of close monitoring of all elements of this scheme should be put in place immediately. A special group should be established for this purpose.	The implementation committee has been set up to fulfil this function.
Regulations should be introduced to require that the prescription and supply of methadone should be restricted to official prescription forms specifically designed for the purpose.	This has been implemented.

Treatment for opiate misuse should be provided in the misuser's own local area wherever possible, as recommended by the Pharmaceutical Society of Ireland, the Medical Council and the Irish College of General Practitioners.	This has been implemented to the extent possible as the majority of general practitioners do not participate in the scheme.
General Practitioners should provide methadone treatment to opiate misusers who reside in their local area, in accordance with the terms of the proposed GP Contract, as set out in this document and as endorsed by the Irish College of General Practitioners.	A contract was agreed and issued to health boards to be signed and returned by general practitioners.
Pharmacists should dispense methadone to opiate misusers who reside in their local area, in accordance with the terms of the proposed Pharmacists' Contract, as set out in this document.	A specific pharmacist contract has not been put in place in most HSE Areas.
The Eastern Health Board (and other health boards where necessary) should ensure that proper structures for effective working relationships between treatment centres and general practitioners and pharmacists are put in place.	This has been implemented to a certain degree but improvements are required.
All patients under treatment for opiate misuse should be transferred to the Methadone mixture DTF 1mg/ml as soon as possible, in strict accordance with the Protocol.	This has been implemented.
GPs and pharmacists should be informed immediately about the philosophy behind the scheme and they should also receive a copy of this report.	This has been implemented.
GPs and pharmacists should be provided with specific training and information on the treatment of opiate dependent persons.	This has been implemented.
The methadone monitoring scheme should be placed on a statutory basis by the making of Regulations under Section 5 of the Misuse of Drugs Act, 1977.	This has been implemented.
All staff involved in the treatment of opiate misusers should be immunised against Hepatitis B. This would include pharmacists and their staff.	Vaccination is offered to staff working with opiate misusers. There is variable uptake as acceptance of vaccination is an individual choice.
A leaflet should be prepared for patients attending pharmacies. This leaflet should outline the main issues involved in the introduction of the new scheme i.e. methadone mixture DTF 1mg/ml, free of charge, treatment card, expiry date, etc.	This has been implemented.
GPs should be issued with a conversion chart from methadone linctus 2mg/5ml to methadone mixture DTF 1mg/ml.	This has been implemented.

6. SUBMISSIONS

6.1. Representation on Implementation Committee

A number of submissions made comments on future representation on the Implementation Committee.

- i. Several of the submissions to the review proposed that there should be representatives on the Implementation Committee, of the community and voluntary sector and of service users.
- ii. It was proposed that there should be a representative of Trinity Court on the Implementation Committee as this is the main centre of treatment and the location of the Central Treatment List.
- iii. It was also suggested that representatives of the three Area Health Boards that make up the ERHA should be members of the Implementation Committee.
- iv. A proposal was made that there should be a representative of the Irish Psychiatric Association on the Implementation Committee.

6.2. Potential Regulatory Changes

Several submissions highlighted recurrent themes in relation to potential regulatory changes.

- i. It was suggested that there be changes in design of the prescription pad to increase confidentiality and efficiency.
- ii. It was proposed that handwriting exemptions for repeat prescriptions be considered.
- iii. The issue of regular clients presenting to pharmacies with no prescription was raised.

- iv. Problems with requisitions were referred to in the submissions.

6.3. Individual Client Issues

A number of submissions dealt with concerns that fall under the heading of individual client issues.

- i. Weekly visits being too frequent, especially if a client is stable and working, was seen as an issue.
- ii. Concerns about reliability of urinalysis and invasion of privacy were raised.
- iii. Client involvement in their treatment protocol, especially dosage levels, should be considered.
- iv. Inefficient appointment systems were raised as an issue.
- v. The lack of provision of systems to deal with chaotic clients was identified as an area that should be looked at.

6.4. General Practitioners

A number of the submissions both from General Practitioners and others highlighted areas of particular relevance to General Practitioners.

- i. The submissions from outside the Eastern Region drew particular attention to a difficulty in recruiting Level 1 and Level 2 General Practitioners (especially Level 2) although this is also a problem in the Eastern Region.
- ii. Increasing the cap on the number of clients attending Levels 1 and 2 GPs was proposed by a few of the submissions.
- iii. There was concern raised about the lack of timely returns to the Health Research Board and suggestions were made that resources should be made available to the GPs to facilitate more timely returns.

- iv. Some submissions suggested that there needed to be more co-ordination outside the Eastern Region and it was proposed that a GP co-ordinator for outside the Eastern Region be appointed.
- v. Increased training for GPs in the area of drug misuse both at vocational training level and undergraduate level was discussed in some submissions.
- vi. It was suggested that training in methadone maintenance would be a desirable qualification for General Practitioners applying for GMS posts, especially in deprived areas.

6.5. Pharmacists

Several submissions highlighted points relevant to pharmacists.

- i. Joint training with other health professionals should be considered.
- ii. The submissions from outside the Eastern Region drew particular attention to the problem of recruitment of pharmacists outside the Eastern Region.
- iii. A number of submissions identified the issue of security in pharmacies as a concern.
- iv. Vaccination for pharmacists and their staff involved in the protocol needs to be looked at again.
- v. Concerns about confidentiality for the clients while attending pharmacies was identified as an issue.

6.6. Miscellaneous Issues

Several submissions highlighted problems throughout the service. The main ones are listed below.

- i. There is a lack of key workers and counsellors in the methadone treatment services.
- ii. There is a lack of co-ordination between psychiatric services and drugs services in rural areas although this was perceived to be a countrywide problem.
- iii. There is a lack of continuity of care especially in relation to discharge from hospitals and prisons and also on admission to these institutions.
- iv. Several of the submissions proposed the increased availability of a range of treatment options including detoxification - both inpatient and outpatient.
- v. It was viewed in some submissions that clients were not progressed on from a methadone maintenance programme and maintenance was considered to be a long-term situation.
- vi. Several submissions also recommended looking at the under 18 years as a special group with some submissions recommending detoxification as the treatment of choice while others proposed that methadone maintenance should be available to this group.

6.7. Outside Terms of Reference

Other issues highlighted by submissions were perceived to be beyond the remit of this review. They were as follows: -

- Fees for GPs
- GP contracts
- Pharmacists' contracts and permanence
- Viral screening and vaccination for service users
- Post detoxification and rehabilitation
- Alternative treatments
- Benzodiazepines
- Alcohol
- The role of the Gardai

These issues will be brought to the attention of the relevant bodies.

7. DISCUSSION

7.1. The Terms of Reference of this review are limited. It is essentially a review of structures and the operation of the Protocol. It does not evaluate methadone as a treatment option or look at other types of treatment. It must also be borne in mind that the review was carried out by the Implementation Committee which was set up to oversee the introduction of the Methadone Prescribing Scheme. Many of the submissions addressed valid issues in relation to drug treatment, which are outside the scope of this review.

In its recommendations the review concentrates on improvements that are required to the service. It should, however, be noted that the majority of submissions acknowledged the success of the protocol and its implementation.

In 2001 the Government published its National Drugs Strategy for the years 2001-2008 in which it endorsed Methadone as the principal opiate substitution treatment and recommended in one of its actions that 6,500 people be in treatment by the end of 2002.

7.2. Representation

The proposals put forward in various submissions in relation to having wider representation on the implementation committee were discussed. It was agreed that a representative of the Drug Treatment Centre Board, the Irish Psychiatric Association (or other body) and the three areas of the HSE Eastern Regional Area should be included on the Committee.

The inclusion of service users and the voluntary and community sector was also

discussed. A recommendation in the National Drugs Strategy is that each health board develop a Service User Charter for those availing of their services. This will address some of the concerns that were raised in submissions. The health strategy has, as an objective, that the patient is at the centre in planning care delivery and that provision will be made for the participation of the community in decisions about the delivery of health and personal social services. As the Methadone Implementation Committee is an operational committee at management level it was not considered appropriate to include service users or a representative of the voluntary sector on the full committee. However, the committee recognises the valuable input from these sectors to the overall delivery and improvement of the services. In this regard it noted that the voluntary and community sector have a close working relationship with the HSE, where their views can be voiced. In relation to service users it was considered that a sub-committee should be set up comprising the Chair of the Methadone Implementation Committee, a consultant in substance misuse, a GP co-ordinator, a liaison pharmacist, a representative of the HSE and service users, to meet on a regular basis to discuss issues of mutual concern.

7.3. Prescription Forms

The proposal from some submissions to introduce handwriting exemptions for methadone prescriptions was discussed. During the course of this discussion it emerged that only a small number of GPs working in treatment clinics would benefit from such an exemption. To introduce this change would require an amendment to the regulations. It was also suggested that if handwriting exemptions were made for methadone that such an exemption would also be demanded for other controlled drugs. It was therefore the view of the Committee that such a recommendation should not be made at this time.

7.4. Requisitions

Some GPs can be requested to attend at Garda Stations to deal with drug misusers who have been arrested and who may require methadone. In order to respond to these situations the GP needs to have methadone in his/her bag. Doctors should only obtain methadone for use in their professional practice on foot of requisitions as provided for in the Misuse of Drugs Regulations 1988. In the absence of an official requisition form, it is suggested that the standard methadone prescription form be used which is written in a manner that clearly shows that the document is a requisition and that methadone is being obtained for professional use.

7.5. Individual Client Issues

The individual client issues raised in many of the submissions could be classed into a few groups. It was believed that some specific issues, such as those dealing with frequency of visits to GPs/clinics, reliability of urinalysis, client involvement in treatment, appointment systems and provision for chaotic clients did not fall within the remit of this committee. The committee acknowledges these concerns however and notes that the National Drugs Strategy, 2001 – 2008 recommends the drawing up of a service-user charter in each HSE area that is specific to treatment and rehabilitation facilities and which would lead to a greater balance in the relationship between the service user and the service provider. The service-user charter is at an advanced stage of preparation or has already been introduced in HSE areas.

7.6. Recruitment of General Practitioners

The review committee recognised that there is a problem with recruitment of General Practitioners and Pharmacists especially outside the HSE Eastern Regional Area. The ICGP has been involved, in conjunction with the HSE (formerly the health boards) and the Department of Health and Children, in looking at ways of encouraging GPs to firstly, expand the number of clients they are seeing up to the maximum number allowed and secondly, to encourage those GPs who underwent training but have not taken on any clients to do so. Research was commissioned by the Eastern Regional Health Authority in partnership with the ICGP, the National Advisory Committee on Drugs and the Health Research Board into GP Participation in the Methadone Maintenance Treatment Protocol and this review will be concluded soon. The involvement of GPs in the Protocol is very important to its operation. The committee accepts that innovative ways need to be found to address this issue in order to ensure the participation of additional GPs in the Protocol.

Currently there is a national GP Co-ordinator who works in the HSE Eastern Regional Area and with the areas outside that region on a wide variety of issues including setting up new services, encouraging GPs to become involved and assisting HSE personnel to deal with problem situations. With the expansion of the services since the introduction of the Protocol and based on suggestions made in some submissions it is thought that the role of the GP co-ordinator should be reviewed. The consideration of this issue and any future arrangements should take place in the context of the new structures in the health service.

One of the principal objectives of the Methadone Protocol, as outlined earlier in this report, was to curb large numbers of individuals attending one GP practice. Treatment of local people in local areas is a key feature of the Protocol and should

remain so. No area should become a focal point for drug misusers. However, it was considered by the committee that the cap on the number of drug misusers attending a GP could be increased in some exceptional circumstances. These circumstances would be looked at on the merits of the situation and would be dependent on the completion of satisfactory audits as laid down by the ICGP. Any increases in the current numbers should only take place with the approval of the ICGP/HSE Review Group.

The committee considered a submission that recommended that GPs applying for GMS posts in deprived areas should have a qualification to treat drug misusers. It was believed by the committee that this could be a useful way of increasing the number of trained GPs in the treatment of drug misusers and that this recommendation should be proposed to the relevant section of the Department of Health and Children.

The review committee welcomes the inclusion of drug misuse and addictions as part of the undergraduate and vocational training syllabus. The training of GPs on the vocational training schemes in methadone prescribing is supported and endorsed.

The making of statistical returns by GPs to the Health Research Board was an issue raised in a few submissions. A contract has recently been negotiated and accepted by GPs involved in the Protocol. As part of this contract GPs will be expected to make timely returns to the HRB.

7.7. Pharmacists

Health boards have been active in trying to engage additional pharmacists in the Scheme. Like the recruitment of GPs, the inability to encourage more pharmacists to become involved in the Protocol, or to accept up to the maximum number of drug misusers who may attend their pharmacy is a difficulty and poses a particular challenge. It is important that ways are found to ensure adequate numbers of pharmacists participate in the Protocol.

There are three liaison pharmacists in the HSE Eastern Regional Area. No equivalent is in place for the rest of the country. This needs to be addressed and it is thought that a liaison pharmacist, who could work with pharmacists outside the Eastern Regional Area, should be appointed.

Vaccination against Hepatitis B for pharmacy staff was also raised as an issue for some pharmacists. This was a recommendation in the Methadone Treatment Services Review Group Report in 1998. The vaccine is available free for Pharmacists from the HSE. While a number of pharmacies have arranged for this vaccination it is suggested that a system be put in place to ensure that pharmacists in as far as possible avail of this vaccine.

In relation to issues of security and confidentiality in pharmacies it was viewed by the committee that these matters were primarily of a resource nature and fall outside the remit of the review. It acknowledges however that these issues are of real concern to pharmacists and to clients. Pharmacists can avail of grants from the HSE to assist with the redesign of their pharmacies in order to create a private section where supervised dispensing can take place. However, it may not always be possible to alter the layout, for example due to the size of a pharmacy premises. Every effort should be made by pharmacists to use the grant to provide, in as far

as possible, a private space for those receiving methadone. In relation to security issues the committee acknowledges the importance of close liaison at local level between the Garda Síochána and community pharmacists. In some areas this liaison is more developed than in others. Efforts should continue to be made to foster contact between the Gardaí and community pharmacists.

The review committee supported ongoing training of pharmacists especially joint training with other health professionals involved in the methadone services and in this regard the Committee considers that the Irish Centre for Continuing Pharmaceutical Education has a central role to play.

It was also acknowledged that on occasion a regular client might present to a pharmacy without a prescription or in circumstances when his/her prescription has expired and it is not possible for a valid prescription to be obtained in order to authorise a supply. This presents a particular difficulty for the pharmacist. The supply to a client of his or her regular methadone dose in such circumstances would be a contravention of the Regulations. However, refusing to supply methadone to the client in such circumstances also raises concerns and presents a considerable ethical dilemma to the pharmacist.

The Committee recognises that a pharmacist has a professional duty of care to the client in such circumstances and would be supportive of a pharmacist who, having exercised due diligence and care, may decide to supply methadone to meet the particular need. Any such supply should be appropriately recorded and followed by receipt of a prescription to cover the supply to the person concerned, and if such circumstances were to be repeated regularly or the necessary follow up prescription was not forthcoming, no further supply on that basis should be made.

7.8. Prescribing of Methadone for Non-Opiate Patients

The regulations in relation to methadone are primarily designed for the treatment of drug misuse. However, over the last number of years an increasing number of consultants have been initiating methadone treatment, particularly for terminally ill patients. The strict rules which apply for opiate users in terms of registering on a central treatment list, issuing of a treatment card etc. do not apply to these patients. However, the special prescription form must be used. GPs and pharmacists who are involved in the treatment of a non-opiate patient prescribed methadone by a consultant are sometimes unaware of the requirements of the protocol. It is important that when such situations arise that the patient can receive his/her appropriate medication without delay and that the professionals involved are knowledgeable of what is required of them.

7.9. Other Issues

Several of the submissions from the health professionals, the NGOs and the service users proposed that a range of treatment options should be available for persons presenting for treatment of drug misuse. The review committee endorsed this view and proposed that although treatment options are available they should be clarified and the range of options explained and discussed with the client within the assessment process. This too is a recommendation in the National Drugs Strategy 2001 - 2008 which states that health boards should have in place a range of treatment and rehabilitation options as part of a planned programme of progression for each drug misuser.

Under 18 year olds presenting for treatment for drug misuse is an issue that was highlighted in a number of submissions. A Working Group chaired by the Department of Health and Children has been established to develop guidelines for

the treatment of this cohort and its report is currently in the process of being finalised.

Several submissions referred to the lack of continuity of care for the treatment of those involved in the Methadone Protocol particularly in relation to those discharged from prison or hospital. The committee acknowledges that this issue is of particular concern. It notes that a committee, chaired by the national GP Co-ordinator, has been established to develop protocols for admission and discharge of methadone patients from prison and this Committee welcomes this development.

Inadequate support in terms of social and psychological care for drug misusers was also raised. The Report of the Methadone Treatment Services Review Group in 1998 recognised that these areas were important in the overall delivery of care to drug misusers. It noted that some health boards (now the HSE) were employing additional counsellors and support workers for this purpose. Additional appointments have been made, however there still remains a gap in terms of sufficient supports being available. This is an area that needs to be addressed by the HSE.

As highlighted by a few of the submissions there is some lack of co-ordination between psychiatric services and drug services for clients who have co-morbidity. The committee acknowledges this as a concern and systems should be put in place by the HSE to ensure co-ordination between the addiction and psychiatric services. The committee also supports the recommendation made in the Report of the National Task Force on Medical Staffing on the appointment of consultant psychiatrists in substance misuse.

8. RECOMMENDATIONS

8.1. Representation on Implementation Committee

- The review committee recommends that there should be representatives on the Implementation Committee from the Drug Treatment Centre Board, the three Areas of the Health Services Executive Eastern Regional Area, the Irish Psychiatric Association (or other body representing psychiatrists),
- A sub-committee should be set up comprising the Chair of the Methadone Implementation Committee, a consultant in substance misuse, a GP co-ordinator, a liaison pharmacist, a representative of the HSE and service users, to meet on a regular basis to discuss issues of mutual concern.
- Sub-committees should be set up to address specific issues that may arise from time to time. For example it is considered that the role of GPs and Pharmacists in delivering services under the protocol could be examined by such a sub-committee. Membership of these sub-committees need not be confined to members of the implementation committee.

8.2. Requisitions

- It is recommended that general practitioners be reminded of the way in which methadone should be obtained for use in their professional practice.

8.3. General Practitioners

- Ways of increasing the numbers of Level 1 and Level 2 General Practitioners, especially outside the HSE Eastern Regional Area should be looked at by the relevant professional body and the HSE. The research into

GP Participation in the Methadone Maintenance Treatment Protocol commissioned by the ERHA could be useful in looking at this area.

- In order to respond to the needs of an expanded drug service throughout the country the nature of the role of the GP Co-ordinator should be considered. Such consideration should take place in the context of the new structures for the health services.
- Currently there is a cap on the number of patients who may be treated by Level 1 and Level 2 GPs. It is recommended that in certain exceptional circumstances these numbers may be increased. Any increases in the current numbers should only take place with the approval of the ICGP/HSE Review Group following an application from the GP/practice concerned. The GP/practice should meet with the necessary audit requirements of the ICGP. At all times the ethos of treating people in their own local area must be maintained.
- Appropriate drug treatment training for General Practitioners applying for GMS appointments in areas of deprivation is desirable and should be considered by the Department of Health and Children.

8.4. Pharmacists

- Ways of increasing the number of pharmacies involved in the scheme, especially outside the HSE Eastern Regional Area, should be looked at by the HSE in consultation with the relevant professional bodies.
- Consideration should be given to the appointment of a Pharmacy Co-ordinator for HSE Areas outside the Eastern Regional Area.

- Consideration should be given to the agreement of a contract between the HSE and pharmacists and such a contract should include provisions for audit.
- The Irish Centre for Continuing Pharmaceutical Education, the body charged with the provision of continuing education to community pharmacists, and the HSE should facilitate training for pharmacists in dealing with drug misusers, and where possible, liaise with relevant organisations in relation to joint training initiatives.
- Arrangements should be put in place as soon as possible for the vaccination against Hepatitis B for pharmacists and their staff involved in the scheme.
- Pharmacists should be encouraged to use the grants available to adapt their premises to ensure, where possible, privacy for clients receiving supervised dispensing.
- Efforts should continue to be made to foster contact and liaison between the Gardaí and community pharmacists via the Local and Regional Drug Task Forces.

8.5. Support Services

- Continuity of care should be a priority so as to provide a seamless service for clients. This is particularly relevant to those clients who are receiving methadone in prisons and are then released into the community at a weekend without prior arrangements being made with HSE services in relation to their care. The Committee welcomes the establishment of a Committee to develop protocols for these situations and will monitor their effectiveness, once introduced, through its ongoing work.

- Leaflets that were prepared for patients following the introduction of the Methadone Protocol in 1998 should be updated and should take account of the Service User Charter that is being put in place in each HSE Area.
- The under 18s group needs special consideration and the recommendations of the Working Group on this issue should be considered when published and the protocol should be adapted accordingly.
- Adequate supports for GPs and pharmacists involved in the protocol are an important element to overall delivery of care. The HSE in line with recommendations contained in the National Drugs Strategy should provide supports.
- Structures should be put in place to give consideration to ways in which co-ordination between the addiction and psychiatric services can be improved in order to ensure that clients with co-morbidity and needing psychiatric treatment are not disadvantaged by being on a methadone treatment programme. The committee also supports the recommendation made in the Report of the National Task Force on Medical Staffing on the appointment of consultant psychiatrists in substance misuse.

8.6. Non-Opiate Patients

- Clear systems to deal with non-opiate dependent patients prescribed methadone should be in place. The Department of Health and Children should develop operation protocols that can be used by relevant professionals involved in the prescribing and dispensing of methadone for non-opiate patients.

9. APPENDICES

1. MEMBERSHIP OF METHADONE PRESCRIBING IMPLEMENTATION COMMITTEE 2003
2. ADVERTISEMENT
3. LIST OF SUBMISSIONS
4. METHADONE PROTOCOL 1998
5. MISUSE OF DRUGS (SUPERVISION OF PRESCRIPTION AND SUPPLY OF METHADONE) REGULATIONS, 1998.

APPENDIX 1

MEMBERSHIP OF METHADONE PRESCRIBING IMPLEMENTATION COMMITTEE 2003.

- ❖ Dr. Joe Barry (Chairman)

- ❖ Dr. Eamon Keenan, Consultant Psychiatrist, South Western Area Health Board

- ❖ Dr. D. Mulholland, Eastern Regional Health Authority

- ❖ Ms. Nihal Zayed, Liaison Pharmacist, Northern Area Health Board

- ❖ Mr. Tom McGuinn, Chief Pharmacist, Department of Health & Children

- ❖ Ms. Noreen Quinn, Pharmacist, Department of Health & Children

- ❖ Ms. Louise Kenny, Department of Health & Children

- ❖ Mr. David Moloney, Department of Health & Children

- ❖ Mr. John Corr, Community Pharmacist, Coolock, Pharmaceutical Society of Ireland and Irish Pharmaceutical Union

- ❖ Mr. David Moore, Administrative Officer, General Medical (Payments) Board

- ❖ Ms. Frances Nangle Connor, Irish Prison Service

- ❖ Dr. I. Delargy, Irish College of General Practitioners
- ❖ Ms. Trish Garland, North Western Health Board
- ❖ Ms. Fiona Walsh, Western Health Board
- ❖ Dr. Neville deSouza, South Eastern Health Board
- ❖ Ms. Kate Mulvenna, North Eastern Health Board,
- ❖ Mr. W. Collins, Southern Health Board
- ❖ Ms. Maria McCully, Mid Western Health Board
- ❖ Dr. Siobhan Rooney, Midland Health Board
- ❖ Ms Fionnuala Rafferty, Drug Treatment Centre Board (Secretary)

APPENDIX 2

ADVERTISEMENT

Review of the Methadone Protocol

The Department of Health and Children has requested the Methadone Prescribing Implementation Committee to conduct a review of the Methadone Protocol that was introduced in October 1998.

The Terms of Reference of the Review are:

- To review the operation of the methadone protocol and its role in providing methadone treatment and rehabilitation of opiate users both in and outside the greater Dublin area
- To review the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998 (S.I. 225 of 1998)* and the report of the Methadone Treatment Services Review Group (1997) in order to advise on their applicability and relevance nationally
- To review the role and working relationships within and between the Department of Health and Children, the Drug Treatment Centre Board, the health boards/ERHA, the Irish College of General Practitioners, the Irish College of Psychiatrists, the Pharmaceutical Society of Ireland, the Irish Prisons Service, general practitioners, pharmacists, community and voluntary groups and other agencies in the provision of methadone treatment
- To consult with relevant stakeholders
- To report and make recommendations as appropriate to the Department of Health and Children by December 2002

* Can be viewed on www.irlgov.ie by clicking on Irish Statute Book link.

Submissions are invited from interested parties to this review and should be forwarded to Room 932, Department of Health and Children, Hawkins House, Dublin 2 or e-mailed to methreview@health.irlgov.ie by Monday 16th September at the latest.

APPENDIX 3

List of Submissions

NO.	NAME
1.	Brian MacDevitt, Bsc (Pharm)
2.	Sr. Margaret M. Reid
3.	Dr. Richard Ennis
4.	Dr. Deborah McGrane, Managing Partner, Parkhouse Family Practice
5.	Anne Harnett, A/Chief Pharmacist and Susan Stack, Senior Pharmacist, Mid-Western Regional Hospital, Limerick.
6.	Dr. Tom O'Dowd
7.	Eddie Guerin, Pharmacist
8.	Michael Tierney, Pharmacist
9.	Addiction Response Crumlin
10.	North Eastern Health Board
11.	Dr. Sile O'Connor
12.	CARP – Killinarden Ltd
13.	Noeleen Harvey, Pharmacist
14.	Drug Prevention Alliance
15.	UISCE/Dublin AIDS Alliance/Citywide Family Support Network
16.	Mary O'Brien, Health Research Board
17.	Dr. Paul Quigley, NAHB Addiction Service
18.	Joseph Treacy, Addiction Counsellor, Western Health Board
19.	John Corr, Pharmacist
20.	Pharmacist of the AIDS/Drugs Service, SWAHB
21.	Dr. Eamon Keenan, Consultant Psychiatrist in Substance Misuse
22.	Athlone Probation and Welfare Service

23. North Western Health Board
24. Irish Prison Service
25. Addiction Spoke
26. David Boles, Pharmacist
27. Kieran Harkin, GP/Eimear Mallon, GP/Catherine Quinn, GP
28. City Wide
29. Irish Pharmaceutical Union
30. Peter Finnegan, Narconon
31. Western Health Board
32. Irish College of General Practitioners
33. Pharmaceutical Society of Ireland
34. Blanchardstown Advocacy Group's Patients Charter
35. Midland Health Board
36. Dun Laoghaire Business Association
37. Mid-Western Health Board
38. South Eastern Health Board
39. Thomas O'Neill/Fergal J. McCoy, Stepping Out Methadone Advocacy Group
40. Eastern Regional Health Authority
41. Dr. John O'Connor, Consultant Psychiatrist/Clinical Director
42. Dr. Fiona Bradley/Dr. Mary Jennings/Dr. David Gibney/
Dr. Deirdre Caulfield/Dr. Brid Hollywood/Dr. Anne Lynott, Ballymun Health Centre
43. Dr. Siobhan Barry, Irish Psychiatric Association
44. Ms. Deirdre Mc Carthy, PAVEE Point
45. Mid-Western Health Board Community Pharmacist
46. Mr. Jason Dyer

Report of the
METHADONE TREATMENT
SERVICES REVIEW GROUP

Department of
Health and Children

An Roinn
Sláinte agus Leanaí

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1. INTRODUCTION

1.1 Terms of Reference of the Review Group

The Review Group was set up to consider the arrangements in place for the management and care of heroin dependent drug misusers by general practitioners and pharmacists and to advise the Minister on the approach to be taken in the future. The group was first convened on 13th January 1997 and its terms of reference were:-

- (a) to examine and define the role of general practitioners and pharmacists in the treatment of opiate dependent persons,
- (b) to examine the working relationships between the various treatment centres and general practitioners and pharmacists, and
- (c) to outline protocols for good practice in the prescribing and dispensing of methadone, including appropriate controls which might be put in place.

1.2 Membership of the Review Group

Membership of the Review group reflected the various agencies which have a role to play in the provision of services for drug misusers. These were the Department of Health, the Eastern Health Board, the Irish College of General Practitioners and the Pharmaceutical Society of Ireland.

Mr Jimmy Duggan, Principal Officer, Community Health Division
(Chairman)

Dr Jim Kiely, Chief Medical Officer, Department of Health

Mr Tom McGuinn, Chief Pharmacist, Department of Health

Ms Noreen Quinn, Pharmacist, Department of Health

Dr Joe Barry, Public Health Specialist, Eastern Health Board

Dr Brion Sweeney, Consultant Psychiatrist, Eastern Health Board
(representing the Consultants working in substance misuse in the Eastern Health Board)

Dr Ide Delargy, Irish College of General Practitioners

Ms Sile O'Connor, Pharmaceutical Society of Ireland (Ms Eugenie Canavan or Ms Leonie Clarke attended meetings when Ms O'Connor was unavailable).

Ms Mary Jackson, Assistant Principal, Community Health Division

Mr Joe Gavin, Higher Executive Officer, Community Health Division, acted as secretary to the group.

The Group met on 13 occasions, which included meetings with representatives from the Merchants Quay Project, Professor Gerard Bury, Department of General Practice, UCD, and the Irish Pharmaceutical Union.

1.3 Protocol for the Prescribing of Methadone

1.3.1 The Report of the Expert Group on a Protocol for the Prescribing of Methadone, which was published in March, 1993, set out recommendations in the form of a Protocol for the involvement of general practitioners and community pharmacists in methadone maintenance programmes (Appendix 1).

This Protocol recommended that general practitioners should become involved by taking on responsibility for the care of opiate dependent persons who had first been stabilised at community drug treatment centres. It also outlined the criteria necessary to ensure that methadone prescribing occurred in a controlled, responsible fashion. Many elements of the protocol have been implemented. Most notably, a central treatment list of patients being prescribed methadone has been established on a voluntary basis. Under this arrangement a general practitioner who is considering prescribing methadone for a patient can check whether the patient's name is on this treatment list and so minimise the possibility that the patient concerned is receiving methadone from more than one source.

1.3.2 In March 1996 a methadone maintenance pilot project, involving general practitioners and pharmacists in the Eastern Health Board region, commenced. It involved the selection of a number of patients who had been stabilised in drug treatment centres and who were referred to general practitioners in their own local area for continuation of methadone treatment and overall medical care.

This pilot programme included the key elements of the Protocol which were:-

- the provision of a personalised treatment card to each patient - this card was

in turn presented to a local pharmacist who held it for the duration of treatment;

- support to GPs and pharmacists through the appointment of a GP facilitator;
- close liaison and communication arrangements with health board services in the event of a patient destabilising;
- contractual arrangements with GPs, pharmacists etc.

1.3.3 Professor Gerard Bury, under the auspices of the Department of General Practice in University College Dublin, carried out an independent evaluation of the pilot protocol programme. This evaluation involved a comparison of general practice care and treatment centre care of stable patients over a period of at least six months. While the final results of the study are not yet available, an initial analysis suggests very similar outcomes for both groups of patients. Feedback from patients and general practitioners involved in the study has also been very positive.

1.3.4 A number of other schemes have developed in parallel with the pilot programme and almost 600 people have been issued with treatment cards to date. Seventy three general practitioners are involved in prescribing and 62 pharmacies are participating in the controlled dispensing of methadone mixture DTF 1mg/ml.

1.4 Ministerial Task Force Report

In order to address the serious problems relating to drug misuse, particularly in the Eastern Health Board area, a Ministerial Task Force on Measures to Reduce the Demand for Drugs was established in 1996. In its first report, published in October, 1996, the Task Force recommended, inter alia, that the GP/ Pharmacist methadone prescription/dispensing scheme should continue to be expanded, evaluated and strictly regulated.

1.5 Pharmaceutical Society of Ireland's Policy on Drug Abuse

In its policy document on drug misuse, which was published in October, 1996, the Pharmaceutical Society of Ireland acknowledged the valuable role played by methadone treatment in the management of opiate addiction. It encouraged pharmacists to participate in methadone dispensing in accordance with specific guidelines (which were in agreement with the recommendations in the Protocol and with Department of Health policy). The document also highlighted important points from a pharmacist's perspective, which would make it more attractive to pharmacists to become involved in methadone dispensing. A copy of the executive summary of this document is attached at Appendix 2.

1.6 Irish College of General Practitioners' Task Group's Report on Drug Misuse

The Irish College of General Practitioners published a Report of the Task Group on drug Misuse in May, 1997. This report recommends that general practitioners should become involved in the treatment of opiate misusers in their own local communities, which is in accordance with joint guidelines of the Medical Council. It also recommended that methadone treatment as described in the Protocol

should continue as a valid form of treatment for opiate dependence. The executive summary of this document is attached at Appendix 3.

1.7 Eastern Health Board Policy

The Eastern Health board is engaged in a major expansion of its services for drug misusers with the aim of eliminating waiting lists for drug treatment by the end of 1997. As part of this programme methadone treatment would be provided to opiate misusers either in drug treatment centres or through arrangements being made with their local general practitioner and pharmacist. The Board has recommended that stricter regulation and control of methadone should be applied in the course of this expansion. In particular, it has recommended that it should be compulsory for doctors to notify the central treatment list of all patients for whom they are prescribing methadone. Further examination of this issue is required.

2. EXTENT OF METHADONE USAGE

A central treatment list for the prescribing of methadone was set up in 1993. Since that date a total of about 4,300 persons have been on methadone treatment. On 13th June 1997 there were 2,232 persons on the central methadone treatment list. Of this group approximately half were receiving treatment in an Eastern Health Board treatment centre, or in the Drug Treatment Centre, Pearse Street. The remainder were being treated by general practitioners

3. GENERAL CONCLUSIONS OF THE GROUP

Having reviewed the issues involved in treatment of opiate dependent persons in their own local communities the Group has come to the following conclusions:-

- (a) methadone treatment continues to be a valid treatment for opiate dependent persons, but it must be part of a comprehensive programme of care;
- (b) the Protocol for the Prescribing of Methadone, as set out in March, 1993 in the Expert Group report, should be the basis on which the further development of services for opiate dependent persons is undertaken, subject to appropriate controls;
- (c) methadone mixture DTF 1mg/ml should be the only strength of methadone used for the treatment of opiate dependence, because of less scope for confusion and accidental overdose and also because it is more appropriate for the treatment of opiate dependence. Methadone linctus 2mg/5ml should be discontinued, except on a “named-patient” basis;
- (d) the sugar-free formulation of methadone mixture DTF 1mg/ml should be used, except in exceptional circumstances. Bottles should be fitted with child-proof caps;
- (e) methadone should be available free of charge to all persons undergoing methadone treatment for opiate dependence;
- (f) the methadone treatment protocol scheme should be available nationally;

- (g) there is a need to strictly control the prescribing and supply of methadone and a system of close monitoring of the prescribing and dispensing of methadone should be put in place immediately. A special group should be established for this purpose;
- (h) regulations should be introduced to require that the prescription and supply of methadone should be restricted to official prescription forms, specifically designed for the purpose;
- (i) methadone linctus 2mg/5ml should cease to be used for the treatment of opiate dependence and manufacturers concerned should be requested to cease the marketing of this product with effect from an agreed date, after which it would only be made available on a “named-patient” basis, in appropriate circumstances.

4. RECOMMENDATIONS ON THE ROLE OF GENERAL PRACTITIONERS

4.1 Involvement of General Practitioners

The involvement of general practitioners in prescribing methadone to opiate dependent persons who live in their local area is vital to the overall success of health board drug treatment programmes. The Group examined present practice among GPs, taking into account advice which it had received through the recommendations in the Irish College of General Practitioners’ Report of the Task Group on Drug Misuse. Issues which were examined included contracting of GPs by the Health Board and support from local health board services for GPs.

4.2 The GP Contract

The Review Group decided to endorse and adopt the scheme of general practitioner involvement outlined in the Irish College of General Practitioners' Report. Under this scheme general practitioners should be contracted by the Health Board to provide treatment on the basis of one of the two levels outlined below.

4.2.1 Level 1 Contract: This level would relate to doctors treating stabilised opiate dependent persons referred from health board drug treatment centres. The contract would include the following elements:-

- the general practitioner should have adequate training in the knowledge, skills and attitudes required to manage opiate misusers in general practice. This would require completion of a recognised training programme agreed between the Irish College of General Practitioners and the Eastern Health Board;
- the general practitioner should ensure that any opiate dependent person he/she is treating is registered on the Central Treatment List (currently held at the Drug Treatment Centre, Pearse Street);
- the general practitioner should satisfy him/herself as to the identity of any opiate dependent person he/she is treating. He/She should also ensure that the person has a treatment card with a recent photograph, name, signature and date of birth, the correct pharmacist's name and address and that this treatment card is not out of date. He/She should also make contact with the pharmacist at an early stage in order to make appropriate arrangements regarding dispensing. This contact should continue during the course of treatment;

- the general practitioner should agree to provide services to a maximum of 15 patients;
- the general practitioner should agree to liaise with a “keyworker”, as set out in protocol, for each patient;
- the general practitioner should agree to a regular audit/evaluation of his/her practice by an Irish College of General Practitioners / Eastern Health Board team;
- the general practitioner should agree to regular educational updates as arranged by the Irish College of General Practitioners/Eastern Health Board team;
- treatment should be provided in local areas as recommended by the Medical Council of Ireland and the Pharmaceutical Society of Ireland;
- the general practitioner should agree that no fees will be accepted from a patient, or any source other than the Health Board, for providing this service;
- prescriptions for methadone should not enable supply for a period greater than seven days, in the course of a single dispensing. Other arrangements may be necessary in exceptional circumstances. In all cases the general practitioner must be satisfied that it is safe to issue the prescription concerned;

4.2.2 **Level 2 Contract** would involve general practitioners who had more training and experience of working with opiate dependent persons. These general practitioners could initiate treatment of opiate dependent persons.

The terms of the Level 2 Contract would include all of the Level 1 terms and in addition:-

- the general practitioner should have undergone a more advanced training programme as agreed between the Irish College of General Practitioners and the Eastern Health Board (including supervision by an experienced general practitioner for 1 year in a treatment centre setting);
- the general practitioner should agree to an annual refresher course and regular evaluation of the practice;
- the general practitioner should treat up to a maximum of 35 patients in his or her own practice;
- general practitioners in a practice with 2 or more doctors could cater for a maximum of 50 patients;
- in certain exceptional circumstances general practitioners may, following consultation with the health board's consultant psychiatrists, be approved to treat a greater number of patients. This may be necessary, particularly in the short term where there is still a difficulty in recruiting new general practitioners to become involved in treatment;

It is intended that only general practitioners who conform to the criteria set out above should treat opiate dependent persons.

5. RECOMMENDATIONS ON THE ROLE OF PHARMACISTS

5.1 Involvement of Community Pharmacists

The involvement of community pharmacists in the dispensing of methadone allows for a large number of opiate dependent persons to be successfully treated in their own local area. Health Boards will enter into a contract with pharmacists to dispense (including the supervised administration of) methadone mixture DTF 1mg/ml to opiate dependent persons in their local area, on special methadone protocol prescription forms, in accordance with the terms set out below.

5.2 Pharmacist's Contract

- Methadone mixture DTF 1mg/ml should only be dispensed on receipt of a correctly written prescription, written on a special prescription form, which would allow for a single supply or supply on installment. The prescription should also indicate whether the administration of the dose should be supervised by the pharmacist or not.
- Methadone should only be dispensed to patients who hold a valid treatment card. Each patient should have a treatment card which would show their name, address, signature and date of birth and contain a recent photograph. This card should also indicate the name and address of the prescribing GP and have an expiry date. The card should be delivered in advance to the pharmacist who should be briefed on how the system works by the GP co-ordinator or the liaison pharmacist.
- The treatment card should be lodged with the pharmacist for the duration of treatment or until it expired or was replaced, or withdrawn.

- Provision should be made for a patient to be referred back to the health board treatment services if the patient fails to comply with an agreed code of behaviour.
- Ideally there should be an upper limit of 50 clients attending any single pharmacy. Provision could, however, be made for numbers in excess of this in certain circumstances, where, for example, it proved impossible to recruit a sufficient number of pharmacists in a locality. The overriding principle should, nevertheless, continue to be that community pharmacists, wherever possible, dispense methadone to patients from their immediate locality.

5.3 Training for Pharmacists

It is essential that pharmacists who wish to become involved in methadone dispensing obtain the relevant training and information in order to assist them in carrying out their role successfully. It is also important that pharmacists get regular updates on drug misuse and specifically on methadone treatment, in order that they keep well informed about current issues. For these reasons it is recommended that training sessions are organised both for pharmacists wishing to become involved in dispensing of methadone and for those already dispensing to opiate misusers.

6. WORKING RELATIONSHIPS BETWEEN TREATMENT CENTRES AND GENERAL PRACTITIONERS AND PHARMACISTS

6.1 Transfer of Patients to General Practice

6.1.1 At present when a patient is transferring to general practice from a health board treatment centre, the Health Board's GP co-ordinator contacts the GP and informs him/her of the details relating to that person. The Health Board provides a designated key worker for each patient and where it is deemed necessary and if the patient so wishes, they will also have access to a community addiction counsellor. Facilities for supervised urines are arranged. The GP enters into a contract with the Board to provide methadone treatment, strictly in accordance with the Protocol. A special prescription form, which is issued by the General Medical Services (Payments) Board, is supplied to the GP.

6.1.2 Contact is made with a local pharmacist who agrees to dispense methadone mixture DTF 1mg/ml strictly in accordance with the Protocol and a contract is entered into between the Health Board and the pharmacist. The opiate dependent person is provided with a treatment card and is registered on the central methadone treatment list. At the same time the Department of Health is notified of the new patient and of the pharmacist involved so that arrangements can be made for the supply of methadone mixture DTF 1mg/ml to that pharmacy. The Department of Health then:-

- notifies, if necessary, the pharmacist's wholesaler that methadone mixture DTF 1mg/ml may be supplied to the pharmacist for a patient;

- notifies the General Medical Services (Payments) Board about the pharmacist's involvement, so that arrangements can be made for payment to the pharmacist for methadone by the Board on receipt of appropriate claim forms;
- writes to the pharmacist stating that methadone mixture DTF 1mg/ml should only be dispensed to the patient or patients named in that letter and asking the pharmacist to confirm his/her agreement to this process.

6.1.3 The pharmacist replies to the Department, agreeing to the terms of the protocol. The patient presents the treatment card to the pharmacist and on receipt of a correctly written prescription form from that patient, methadone is dispensed. If, for any reason, the patient de-stabilises or problems are created, the pharmacist contacts the Health Board co-ordinator in order to make arrangements for the patient's return to health board services.

These arrangements were put in place to ensure that strict controls applied to the operation of the scheme. It is recommended that these should continue under the aegis of the Eastern Health Board.

6.2 Future Plans for Co-ordination of Methadone Schemes

The Eastern Health Board and the Drug Treatment Centre in Pearse Street will provide on-going support to GPs and pharmacists involved in methadone treatment as follows:-

- (a) the Eastern Health Board has been divided into 3 sectors for the purpose of co-ordinating drug misuse services. Within each sector the Consultant

Psychiatrists, Area Operations Managers and GP-ordinators, together with two Liaison Pharmacists, will ensure effective management of services;

- (b) patients will be provided with support from health board counselling and outreach staff. The Board is in the process of employing additional counsellors and support workers for this purpose. Voluntary agencies working in the locality of drug users will also be supported to provide this service. The board has also installed a telephone helpline service, operating from 10.00 a.m. to 5.00 p.m., Monday to Friday, which can deal with crises calls from drug misusers or family members and direct them to the appropriate services;
- (c) information will be prepared for pharmacists which will include guidelines on the handling of methadone and on supervised consumption;
- (d) information will also be provided to GPs, which will include guidance on upper limits of dosage, urine screening, maximum number of patients;
- (e) The Health Board will provide GPs with an audit form, which will be completed on an annual basis in conjunction with the GP co-ordinator and the Eastern Health Board's Consultant Psychiatrists in accordance with the recommendations of the Irish College of General Practitioners/Eastern Health Board team;
- (f) a comprehensive treatment plan will be put in place in respect of each patient. This will include medical, social and psychological care. A regular review will also be made of each patient's progress on methadone treatment.

7. PLAN FOR INTRODUCTION OF THE SCHEME

7.1 Wider Implementation of the Methadone Protocol

7.1.1 The Group recommends that all patients under treatment for opiate misuse should be transferred to the methadone mixture DTF 1mg/ml product as soon as possible, in strict accordance with the Protocol.

7.1.2 Every general practitioner and pharmacist will be informed of the philosophy behind the new system and of the procedures to be undertaken. All general practitioners and pharmacists will receive a copy of the Protocol for the Prescribing of methadone and details of the arrangements, including the contact persons and their telephone numbers in case of emergency. As and from a specified date methadone mixture DTF 1mg/ml only will be available and all supplies of DTF will be restricted to patients who have valid treatment cards. It is anticipated that there would be a “lead in” time of some months to accomplish the issuing of treatment cards and auditing of GPs who wish to become involved.

7.1.3 Training seminars for both GPs and pharmacists will be arranged by the Eastern Health Board on a regular basis, commencing immediately.

8. SCHEME OF MONITORING AND CONTROL OF METHADONE USAGE

8.1 Statutory Basis for Scheme of Monitoring

It is recommended that a scheme of monitoring of methadone usage be introduced and that it should be placed on a statutory basis by Regulations under Section 5 of the Misuse of Drugs Act, 1977. The Review Group agreed that the following

should form the basic elements of a scheme designed to monitor the prescribing and use of medicinal products containing methadone, its salts and preparations.

- (a) prohibition of the writing of prescriptions for methadone except on a prescribed prescription form supplied by, or on behalf of the Minister (i.e. the prescribed form);
- (b) prohibition of the dispensing of any prescription for methadone unless it has been written on the prescribed form;
- (c) the prescribed prescription form should be available on a multiform basis. One copy would be supplied to a single national centre for review and monitoring. While a separate form may be made available for use in installment dispensing, consideration will be given to the incorporation of single dispensing and installment dispensing facilities within the one prescription form;
- (d) any pharmacist who dispenses a prescription for methadone would be required to forward a copy of that prescription to the designated national centre (probably at the end of each month) for the purpose of review and monitoring;
- (e) in order to assist in the measurement of the extent of opiate misuse doctors would be required to complete a Health Research Board report form once a year in respect of each person for whom they had prescribed methadone.

9. OTHER RECOMMENDATIONS FOR THE EXTENDED IMPLEMENTATION OF THE METHADONE PROTOCOL

The group has also made the following recommendations:-

- (a) all staff involved in the treatment of opiate misusers should be immunised against Hepatitis B. This would include pharmacists and their staff;
- (b) a leaflet should be prepared for patients attending pharmacies. This leaflet should outline the main issues involved in the introduction of the new scheme i.e. methadone mixture DTF 1 mg/ml, free of charge, treatment card, expiry date, review of treatment cards, etc;
- (c) GPs should be issued with a conversion chart from methadone linctus 2mg/5ml to methadone mixture DTF 1mg/ml.

10. SUMMARY OF MAIN RECOMMENDATIONS OF THE METHADONE TREATMENT SERVICES REVIEW GROUP.

1. Methadone treatment should continue to be a valid treatment for opiate dependence, as part of a comprehensive programme of care. [3.(a)]
2. The Protocol for the Prescribing of Methadone as set out in March, 1993 should be the basis on which the further development of services for opiate dependent persons is undertaken, subject to appropriate controls. [3.(b)]
3. There should be only one form of methadone used for the treatment of

opiate dependence - methadone mixture DTF 1mg/ml. Methadone linctus 2mg/5ml should be discontinued, except on a “named-patient” basis. [3.(c) and (i)]

4. The sugar-free formulation of methadone mixture DTF 1mg/ml should be used, except in exceptional circumstances and bottles should be fitted with child-proof caps. [3.(d)]
5. Methadone should be available free of charge to all persons undergoing methadone treatment for opiate dependence. [3(e)]
6. The methadone treatment protocol should be available nationally.[3.(f)]
7. The prescription and supply of methadone should be strictly controlled and a system of close monitoring of all elements of this scheme should be put in place immediately. A special group should be established for this purpose. [3.(g)]
8. Regulations should be introduced to require that the prescription and supply of methadone should be restricted to official prescription forms specifically designed for the purpose. [3.(h)]
9. Treatment for opiate misuse should be provided in the misuser’s own local area wherever possible, as recommended by the Pharmaceutical Society of Ireland, the Medical Council and the Irish College of General Practitioners. [1.5 and 1.6]
10. General practitioners should provide methadone treatment to opiate misusers who reside in their local area, in accordance with the terms of the

proposed GP contract, as set out in this document and as endorsed by the Irish College of General Practitioners. [4.2]

11. Pharmacists should dispense methadone to opiate misusers who reside in their local area, in accordance with the terms of the proposed Pharmacist's Contract, as set out in this document. [5.2]
12. The Eastern Health Board (and other health boards where necessary) should ensure that proper structures for effective working relationships between treatment centres and general practitioners and pharmacists are put in place. [6.2]
13. All patients under treatment for opiate misuse should be transferred to the Methadone mixture DTF 1 mg/ml as soon as possible, in strict accordance with the Protocol. [7.1.1]
14. GPs and pharmacists should be informed immediately about the philosophy behind the scheme and they should also receive a copy of this report. [7.1.2]
15. GPs and pharmacists should be provided with specific training and information on the treatment of opiate dependent persons. [4.2, 5.3 and 7.1.3]
16. The methadone monitoring scheme should be placed on a statutory basis by the making of Regulations under Section 5 of the Misuse of Drugs Act, 1977. [8.1]
17. All staff involved in the treatment of opiate misusers should be immunised

against Hepatitis B. This would include pharmacists and their staff. [9.(a)]

18. A leaflet should be prepared for patients attending pharmacies. This leaflet should outline the main issues involved in the introduction of the new scheme i.e. methadone mixture DTF 1mg/ml, free of charge, treatment card, expiry date, etc. [9(b)]

19. GPs should be issued with a conversion chart from methadone linctus 2mg/5ml to methadone mixture DTF 1mg/ml. [9.(c)]

In the course of this review it was noted that it may be necessary at a future date to introduce monitoring of other drugs used in the treatment of drug misuse in a similar fashion. However, the Group felt that the controls and regulations which will be introduced regarding methadone and the training and education programmes which will be delivered to both general practitioners and pharmacists will, in turn, lead to a general improvement in the system.

REPORT OF THE EXPERT GROUP ON THE ESTABLISHMENT OF A PROTOCOL FOR THE PRESCRIBING OF METHADONE

26 March 1993

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.

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 was 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 co-operative 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:-

1. That maintenance programmes represented, for many users, their most feasible option for stabilising their addiction. These programmes had obvious attractions for service users.
2. 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.

3. 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); Buprenorphine (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 co-operation 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 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 co-operation 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 the 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 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, 1998. 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 (IPU) 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 had 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 recommended 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 services.
- (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 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 opening report are operating satisfactorily.

GOOD CLINICAL PRACTICE IN RELATION TO METHADONE PRESCRIBING

**Dr. John J. O'Connor, Consultant Psychiatrist/Clinical Director Drug
Treatment Centre, Trinity Court**

January 1993

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 is 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 dependant 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 a adjunct to treatment and not treatment per se.

RECOMMENDATIONS

OF THE MEDICAL COUNCIL FOR THE PRESCRIBING OF CONTROLLED DRUGS UNDER THE MISUSE OF DRUGS ACTS, 1977 AND 1984

- 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.

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

Misuse of Drugs Acts, 1977 and 1984

PRESCRIPTION WRITING REQUIREMENTS

It is unlawful for a practitioner to issue, or for a pharmacist to dispense, a prescription for a Schedule 2 or 3 drug unless it complies with the following requirements:

The prescription *must*:

A be in ink or otherwise indelible and be signed by the practitioner with his/her usual signature and dated by him/her.

B clearly indicate the name of the practitioner issuing it and, except in the case of a health prescription (GMS), specify his/her address.

C specify (in the prescriber's handwriting) the name including given name, and address of the person for whose treatment it is issued.

D state that the person issuing it, is a registered medical practitioner, and a telephone number at which the practitioner may be contacted.

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 installments, specify the amount of the installments and the intervals at which the installments may be dispensed.

Notes:

1. The practitioner must also be satisfied as to the identity of the person for whose treatment the prescription is being issued. The pharmacist must also be satisfied in this regard.
2. Prescriptions for controlled drugs may not be repeated.

INCORRECT

Mr. John McKenna,
84, Maryfield Estate,
Drogheda,
Co. Louth.

(B)
Tel No. (D)
(A)

Rx Sevredol Tablets (Eii) (Eiii)
Mitte 60 (E) (Eiv)
Sig: 1 tablet when pain is troublesome (Ei)
Repeat 3 times (F)

(A) Margaret Hill (D)

CORRECT

Mr. John McKenna,
84, Maryfield Estate,
Drogheda,
Co. Louth.

(B) Ardnaree,
Collon,
Co. Louth (D)
Tel No. (041) 123456 (D)
8th April 97 (A)

Rx Sevredol Tablets 10 mg (Eii) (Eiii)
Mitte 60 (sixty) (E) (Eiv)
Sig: 1 tablet 4 hourly (Ei)
Supply in three installments of 20 tablets at intervals of three days. (F)

(A) Margaret Hill M. D. (D)

NOTE: INCORRECTLY WRITTEN PRESCRIPTIONS ARE ILLEGAL

A LIST OF THE MOST COMMON CONTROLLED DRUGS

SCHEDULE 2

Class of Controlled Drug	Proprietary Products
Alfentanyl	Rapifen
Amphetamine	
Buprenorphine	Temgesic
Cocaine	
Codeine	
Dextromoramide	Palfium
Dihydrocodeine	DF 118, DHC Continus
Dipipanone	Diconal
Fentanyl	Sublimaze, Durogesic
Hydrocodone	
Hydromorphone	Dilaudid, Palladone, Palladone SR
Levactylmethadol	Orlaam
Levorphanol	Dromoran
Medicinal Opium (which includes Papaveretum and Opium Tincture BP)	Omnopon
Methadone	Physeptone
Methylphenidate	Ritalin
Morphine	Cyclimorph, Morstel SR MSTContinus, MXL, Sevredol, Oramorph Concentrate, Oramorph UDV
Pethidine	
Pholcodine	
Phenoperidine	Operidine
Quinalbarbitone	Seconal, Tuinal
Sufentanil	Sufenta

SCHEDULE 3

Amylobarbitone	Sodium Amytal
Diethylpropion	
Flunitrazepam	Rohypnol
Mazindol	Teronac
Meprobamate	Equagesic, Equanil
Pentazocine	Fortral, Fortagesic
Phenobarbitone	Gardenal Sodium 200mg
Phentermine	Duromine, Ionamin
Temazepam	Euhypnos, Normison, Nortem, Tenox

NOTE: The stricter rules for writing prescriptions do not apply to the following:

- (i) preparations containing not more than 100mg per dosage unit of methylphenobarbitone or phenobarbitone (each calculated as base).
- (ii) preparations containing not more than 0.1% of cocaine or 0.2% of morphine (each calculated as base).
- (iii) preparations (other than injections) containing not more than 100mg per dosage unit of codeine or pholcodine (each calculated as base) or in divided preparations not more than 2.5% of either drug.
- (iv) preparations (other than injections) containing not more than 10mg per dosage unit of dihydrocodeine (calculated as base) or in undivided preparations not more than 1.5%.

RECOMMENDATION OF THE PHARMACEUTICAL SOCIETY OF IRELAND POLICY ON DRUG ABUSE

October 1996

12. Summary of Recommendations

The Following are the main recommendations of the Pharmaceutical Society of Ireland on how best the problem of drug abuse may be addressed and how the role of the pharmacist may be employed in this. These are taken from the main body of the policy document and each recommendation is followed by a reference to its location in the document.

12.1 Role of the Pharmacist

12.1.1 Sale of medicines

All medicines should be sold from pharmacies and pack size, supplies and usage should be limited to safe, effective levels. (5.5.1)

12.1.2 Counselling on medicines usage

All medicines should be issued to the public with counselling and the pharmacist should be available for consultation with the patient. (5.5.2)

12.1.3 Licensing of pharmacies

A licensing system should be introduced for pharmacies to give an even geographical distribution, highest professional standards and the maximisation of professional services offered. (5.5.3)

12.1.4 Role of the pharmacist

The role of the pharmacist within the community is a most valuable asset which must be utilised to its full potential if the problem of drug abuse is to be tackled effectively. (5.5.4)

12.1.5 Training and service co-ordinator

One or more full-time co-ordinators should be appointed to oversee all aspects of pharmacy involvement in the drug abuse prevention and treatment services. (6.5)

12.1.6 Identification of samples

Requests for identification of suspicious samples from members of the public should be facilitated insofar as possible. (8.3)

12.1.7 Health promotion

A health promotion section for the display of promotional and educational materials should be available to the public in all pharmacies. (8.7.3)

12.2 Education issues

12.2.1 Surveys on drug use among adolescents

Biennial surveys to be carried out to monitor the extent of drug use among adolescents at school and young people outside the school system. (4.2.4.2)

12.2.2 Information on drugs

Pharmacists form a ready-made community network providing easy access to drug information for the general public and as such are ideally placed to play a major role in drug education. (6.6.1)

12.2.3 Survey of training needs

In order to ascertain what level and type of training is required so as to enable pharmacists to become effective community educators, it might be necessary to undertake a survey of pharmacists on this matter. (6.2.4)

12.2.4 Training programme for pharmacists

A training programme for pharmacists who wish to become involved in drug education should be organised. This would provide pharmacists with the necessary presentation and attitude insight skills to enable them to successfully impart their knowledge to others. A suitable support package should be developed for appropriately trained pharmacists. (6.3)

12.2.5 Liaison with other groups

Liaison with the Health Promotion Unit of the Department of Health should be encouraged to enable pharmacists to avail of the

excellent range of promotional and educational materials provided by the Health Promotion Unit. (6.4)

12.2.6 Sharing presentations

Pharmacists should not share presentations with speakers who also discuss the effects of drugs unless these speakers are qualified to do so. (6.6.7)

12.2.7 Information on drug use statistics

Liaison with the Garda Síochána should be organised to enable pharmacists to avail of up-to-date statistics on drug use in local areas. (6.6.6)

12.2.8 Substance Abuse Prevention Programme

The efforts of the Departments of Education and Health in organising the Substance Abuse Prevention Programme for secondary schools and the dedication of the hundreds of teachers who participated in it are to be applauded. A similar programme for primary school children, their parents and teachers would be another important step in demand reduction. (6.4.3)

12.2.9 Participation in Substance Abuse Prevention Programme

Pharmacists throughout the country should contribute to the successful implementation of these programmes by building on the existing technical support given by individuals to the project development. (6.6.8)

12.2.10 Heroin smoking

An education campaign on the dangers of heroin smoking to be initiated as a matter of urgency. (4.2.4.5)

12.3 Maintenance and care of addiction

12.3.1 Participation in methadone dispensing

All pharmacists should be encouraged to dispense methadone for patients in accordance with the guidelines for dispensing of methadone detailed in the report. (7.1.2 and 7.1.3)

12.3.2 Clinical information

Information on all aspects of methadone programmes should be made available to pharmacists to enable them to more fully understand the management of opiate addiction. (7.1.1.4)

12.3.3 Methadone formulations

Methadone 1mg/1ml is the preferred strength for use in treatment programmes. (7.1.1.4)

12.3.4 Alternative treatments

It is hoped that non-opioid alternatives to methadone for the management of addiction will be considered in the future. (7.1)

12.3.5 Pharmacist/patient contract

Any pharmacist dispensing methadone for a patient should ensure that both they themselves and the patient have signed a pharmacist/patient contract. (7.1.5)

12.3.6 Needle and syringe exchange

The principle of needle and syringe exchange is recognised as a proactive approach to health promotion and a properly co-ordinated, funded and supervised national needle and syringe exchange network with clear policies on the primary practice issues of supply, receipt, safe custody and disposal should be established. (7.2)

12.3.7 Local drug services

Pharmacists should draw up a list of drug treatment and counselling services in their local area, to be used in conjunction with presently available directories to assist people who approach them for advice on these services. (8.2)

12.3.8 Counselling services

The level of services, both general and specialised, for drug abuse counselling should be greatly increased. (8.4)

12.3.9 Methadone treatment charges

Methadone should be supplied free of charge to all persons undergoing a recognised drug treatment programme. (7.3.1.1)

12.4 Legal issues

12.4.1 Solvents

Self-service sales of solvents to be banned. (4.2.4.1)

12.4.2 New schedule to the Misuse of Drugs Regulations

Certain drugs which are used in the treatment of drug addiction should be entered in a new schedule to the Misuse of Drugs Regulations, 1988-1993, to be called Schedule 6. (9.2)

12.4.3 Powers of the Pharmaceutical Society of Ireland

The Misuse of Drugs Regulations, 1988 should be amended to give powers of inspection and entitlement to information in respect of controlled drugs in community pharmacies, hospitals and pharmaceutical wholesalers to the Pharmaceutical Society. (9.3)

12.4.4 Dispensing of controlled drugs

Dispensing of controlled drugs should take place in a community pharmacy, a hospital pharmacy department or an official health board drug treatment service. (9.4)

Dispensing should be carried out by a pharmacist, and where this is not possible, the dispensary service should be overseen by a co-ordinating pharmacist. (9.4)

12.4.5 Treatment referral

Drug addicts convicted of minor drugs related offenses should have the option, when this is considered suitable, of taking a place on a recognised drug treatment service instead of a custodial sentence. (9.5)

12.4.6 Drug-free units in prisons

Insofar as it is practically possible, each prison in the State should have a specially designated drug-free unit. (9.6)

12.4.7 Government initiatives

While the present government initiatives on tackling drug abuse are welcomed, it is regrettable that very little cognisance is taken of the possible contribution which pharmacists could make to a resolution of the problem. (9.7)

12.4.8 Present legal classifications

No change should be made to the legal status of any substance listed in Schedule 1 to the Misuse of Drugs Regulations, 1988-1993. (9.8)

12.4.9 Elimination of illicit drug supply

Further emphasis to be placed on elimination of the supply side of the drugs problem at all levels, retail, wholesale and import. (4.2.4.3)

RECOMMENDATIONS OF THE IRISH COLLEGE OF GENERAL PRACTITIONERS' TASK GROUP ON DRUG MISUSE

May, 1997

Some recommendations are followed by a reference to their locations in the ICGP report.

Summary of Recommendations

1. General Practice has an important contribution to make in the management and prevention of drug misuse, together with other medical, social, and political agencies.
(Section 1).
2. The causes of drug misuse have major social, economic, and educational roots, as well as medical, and proposed solutions to the problem must address all of these factors.
(Section 2).
3. Alcohol and benzodiazepines (whether prescribed or obtained illegally) are the most common causes of drug misuse in Ireland, but this document deliberately confines itself to the problem of opiate addiction.
4. The Task Group recommends a model of care for opiate addicts based in general practice, with GPs providing methadone maintenance (Level 1)

where appropriate, or methadone initiation as well as maintenance (Level 2) where appropriate.

(Section 4).

5. There must be an adequate number of GP facilitators appointed, who have the necessary expertise and commitment to enroll, support, liaise with, and advise GPs.

(Section 4).

6. There must be a confidential national treatment list on which all patients receiving methadone will be entered.

(Section 4).

7. All patients receiving methadone must have an individualised treatment card, which is supplied to and kept at their pharmacy.

(Section 4).

8. Methadone treatment, including prescriptions, should be free of charge to opiate addicts.

(Section 4).

9. Prescribing of methadone should be budget neutral to GPs.

(Section 4).

10. Methadone must be dispensed at a local pharmacy, and where indicated in daily doses, preferably with supervised ingestion on the premises.

(Section 4).

11. There must be local access to the full range of services needed to assess, treat, and follow-up opiate dependent patients.
(Section 4).
12. There must be a flexible, quick, and easily accessible referral and re-referral system available to GPs.
(Section 4).
13. There must be suitable training and education for participating doctors, including assessment for certification and re-certification.
(Section 4).
14. There must be adequate, negotiated, and agreed payment for certified participating doctors.
(Section 4).
15. The number of addicts being treated by any single GP should not exceed 10-15 for Level 1 doctors, or 30-35 for Level 2 doctors.
(Section 4).
16. The criteria for patients suitable for treatment in general practice by Level 1 and by Level 2 GPs are proposed.
(Section 5).
17. A joint ICGP/Health Board Review Group is proposed, which would have responsibility for overseeing and approving education and assessment, as well as policy development.
(Appendix C).

18. The field of drug misuse is dynamic and rapidly changing, and ICGP policy in this area will need to be kept under continuous review.

19. The ICGP expects that this policy document, together with the Fact Files, will encourage its members to take part in the medical management of drug misusers at all levels, and to participate in the Methadone Protocol where clinically appropriate.

APPENDIX 5

STATUTORY INSTRUMENT

S.I. No. 225 of 1998

MISUSE OF DRUGS (SUPERVISION OF PRESCRIPTION AND SUPPLY OF METHADONE) REGULATIONS, 1998

Dublin

Published by the Stationery Office

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Price £2.00
Postage £0.48p

S.I. No 225 of 1998.

**Misuse of Drugs (Supervision of Prescriptions and Supply of Methadone)
Regulations, 1998**

I, Brian Cowen, TD, Minister for Health and Children, in exercise of the powers conferred on me by section 5 of the Misuse of Drugs Act, 1977 (No.12 of 1977), and the Health (Alteration of Name of Department and Title of Minister) Order, 1997 (S.I. No. 308 of 1997), hereby make the following regulations:

Commencement.

1. (1) These Regulations may be cited as the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998.

- (2) Save where otherwise expressly provided, these Regulations shall come into operation on the 16th day of July, 1998.

Interpretation.

2. (1) In these Regulations, unless the context otherwise requires -
“Act of 1977” means the Misuse of Drugs Act, 1977 (No. 12 of 1977);
“Central Treatment List” means the record referred to in Regulation 3(2);
“drug treatment card” means a card which has issued to a person pursuant to Regulation 4;
“Eastern Health Board” means the health board established under Regulation 4 of the Health Boards Regulations, 1970 (S.I. No.170 of 1970);

“health board” means a health board established under section 4 of the Health Act, 1970 (No. 1 of 1970);

“Minister” means the Minister for Health and Children;

“person keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons” has the same meaning as in Regulation 3 of the Regulations of 1988;

“prescription” means a prescription issued by a registered medical practitioner in compliance with Regulation 13(1) (form of prescriptions) of the Regulations of 1988;

“Regulations of 1988” mean the Misuse of Drugs Regulations, 1988 (S.I. No. 328 of 1988);

“specified controlled drug” means a drug specified in the Schedule of these Regulations.

- (2) In these Regulations, unless the context otherwise requires -
- (a) a reference to a Regulation is a reference to a Regulation of these Regulations,
 - and
 - (b) a reference to a paragraph is a reference to a paragraph of the provision in which the reference occurs.

Central Treatment List.

3. (1) Where a registered medical practitioner intends to prescribe a specified controlled drug for the first time to a person who has presented to the registered medical practitioner for treatment, the registered medical practitioner shall not issue a prescription for the drug until he or she notifies the Eastern Health Board of the name, address and date of birth of the person.
- (2) The Eastern Health Board shall maintain a record to be known and in these Regulations referred to as the “Central Treatment List” which shall contain the information notified to it under paragraph (1) and the list may be maintained in electronic form.
- (3) Where a notification is made to the Eastern Health Board in accordance with paragraph (1), the Eastern Health Board shall inform the registered medical practitioner as to whether the person has previously been included in the Central Treatment List.
- (4) The Eastern Health Board may amend an entry in or delete an entry from the Central Treatment List.

Issue of drug treatment card.

4. (1) A health board shall issue a drug treatment card in respect of a person participating in a programme of treatment involving the use of a specified controlled drug and in respect of whom the information referred to in Regulation 3(1) has been notified to the Eastern Health Board.

- (2) A drug treatment card shall be valid for such period as may be specified on the card but in any case shall not be valid for more than one year from the date of issue.

General prohibition on registered medical practitioner

5. (1) A registered medical practitioner shall not issue a prescription for a specified controlled drug other than on a form supplied by or on behalf of the Minister.
- (2) From the 1st day of October, 1998, a registered medical practitioner shall not issue a prescription referred to in paragraph (1) other than to a person in respect of whom a drug treatment card has been issued and remains valid.
- (3) Notwithstanding Regulation 13 of the Regulations of 1988, it shall be sufficient compliance with the requirements of paragraph (1)(f) of that Regulation if the information required to be included on a prescription issued by a registered medical practitioner in accordance with paragraph (1) of this Regulation is impressed upon the prescription from an embossed drug treatment card.

General prohibition on person keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons.

6. (1) Subject to paragraph (3), a person keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons shall not supply a specified controlled drug on a prescription other than on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1).
- (2) From the 1st day of October, 1998, a person keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons shall not supply a specified controlled drug on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1) other than to a person in respect of whom a drug treatment card has issued and remains valid.
- (3) Paragraph (1) shall not apply to a prescription issued by a registered medical practitioner before the coming into operation of that paragraph.

Information to be furnished to Minister

7. (1) Subject to paragraph (2), a person keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons shall forward to the Minister -
 - (a) in respect of each supply of a specified controlled drug -
 - (i) the original prescription on which the supply of the specified controlled drug was made, and

(ii) in respect of the prescription, a statement which confirms or clarifies the identity of the person to whom the prescription was issued, if the information given on the prescription is inadequate, illegible or misleading,

and

(b) particulars of each supply of a specified controlled drug made to a registered medical practitioner pursuant to a requisition referred to in Regulation 12(2) (documents to be obtained by a supplier) of the Regulations of 1988, not later than 14 days after the last day of the calendar month in which the supply of the specified controlled drug made on that prescription was completed or when no further supply may be made on that prescription.

(2) Paragraph (1) shall not apply to a prescription issued by a registered medical practitioner before the coming into operation of this Regulation.

Minister to maintain a record

8. (1) The Minister shall maintain a record of all prescriptions received by him or her under Regulation 7 and the record may be maintained in electronic form.

(2) Subject to paragraph (3), the Minister may amend an entry in or delete an entry from the record referred to in paragraph (1).

(3) Each prescription received by the Minister under Regulation 7 shall be preserved for a period of two years from the date of receipt of that prescription.

Prohibition on supply

9. (1) A person shall not supply a specified controlled drug to a registered medical practitioner unless that person is a person keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons.
- (2) Paragraph (1) shall not apply to a person who is the holder of a license under section 14 of the Act of 1977 to supply a controlled drug, where the licence directs that such supply may be made.

Supply by instalments

- 10.(1) From the 1st day of October, 1998, for the purposes of compliance with Regulation 16(1) (keeping of registers) of the Regulations of 1988, where the supply of a controlled drug on a prescription issued by a registered medical practitioner in accordance with Regulation 5(1) is to be dispensed in instalments -
- (a) the information in relation to each supply may be entered on the prescription, and
- (b) the total amount supplied on the prescription, when the dispensing of that prescription has been completed or when no further supply may be made on that prescription, may be entered, in the register referred to in Regulation 16(1) of the Regulations of 1988, as the amount supplied.
- (2) For the purposes of an entry in a register to be made under paragraph (1), the date to be entered in the register shall be the date on which the last supply was made on the prescription concerned.

Preservation of registers

11. Notwithstanding Regulation 19(2) (preservation of registers) of the Regulations of 1988, the preservation of a copy of a prescription issued by a registered medical practitioner in accordance with Regulation 5(1), made by a registered medical practitioner at the time of writing the original prescription, shall be treated as if it were the preservation of the original prescription.

Exemption: hospitals

- 12.(1) These Regulations shall not apply to a prescription issued in respect of a specified controlled drug where the prescription has been issued in a hospital
 - (a) for administration in the hospital, to the person to whom the prescription relates, or
 - (b) for supply in the hospital, in exceptional circumstances, to the person to whom the prescription relates, and who has attended the hospital -
 - (i) for the treatment of opiate dependence, or
 - (ii) as an in-patient who is opiate dependent.
- (2) In this Regulation “hospital” means a hospital, nursing home or clinic which is wholly or mainly maintained by a public authority out of public funds, by a charity or by voluntary subscriptions.

Exemption: medical consultants

13. (1) Regulations 3, 4, 5(2) and 6(2) shall not apply to a prescription issued for the treatment of a person for purposes other than for or in connection with opiate dependence provided that -
- (a) the prescription has been initiated, for issue by a registered medical practitioner, by a medical consultant whose name and address is included on the prescription, or
 - (b) the prescription is issued by the medical consultant.
- (2) In this Regulation “medical consultant” means a registered medical practitioner in any hospital practice who by reason of his or her training, skill and experience in a particular speciality, is consulted by other registered medical practitioners.

SCHEDULE

Regulation 2

1. Methadone.
2. Any stereoisomeric form of a substance specified in paragraph (1).
3. Any salt of a substance specified in paragraph 1 or 2.
4. Any preparation or other product containing any proportion of a substance or product specified in paragraphs 1, 2 or 3.

GIVEN under the Official Seal
of the Minister for Health and Children
this 1st Day of July, 1998

Brian Cowen TD.
Minister for Health and Children.

L.S.

