

Guidance for Pharmacists on the Safe Supply of Methadone

1. Introduction

The purpose of this guidance is to remind registered pharmacists involved in the supply of methadone, and the provision of associated services to patients, of the requirements which must be fulfilled in order to ensure compliance with legal and professional obligations.

2. Methadone

Methadone is a Schedule 2 controlled drug which is used in the treatment of opioid addiction as substitution or maintenance therapy, within a broader treatment protocol, accompanied by regular reviews and reassessment. This treatment must be supervised by specialist services. Certain methadone products are also licensed for the relief of severe pain in conditions where morphine may be a reasonable alternative, such as severe cancer pain.¹

3. Legal Considerations

The principal legal requirements governing the supply of methadone and the provision of related services are contained in the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No. 225 of 1998). It is an offence to supply methadone otherwise than in accordance with these regulations. Pharmacists must also comply with the requirements of the Pharmacy Act 2007, the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) and the Misuse of Drugs Acts and the orders and regulations made thereunder, including the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended).

In addition, pharmacists must ensure their professional practice in relation to patients is in compliance with the Methadone Protocol², the guidance of the PSI (as the statutory regulator) and the statutory Code of Conduct for pharmacists.

4. Code of Conduct for Pharmacists

Throughout the process of managing the supply of methadone and the provision of related services to patients, pharmacists must ensure that, in accordance with the first principle of the statutory Code of Conduct for pharmacists, the practice of their profession is directed toward maintaining and improving the health, wellbeing, care and safety of patients.

¹ The therapeutic indications are as per the Summaries of Product Characteristics for methadone products (available via the Irish Medicines Board website www.imb.ie).

² The Methadone Protocol is the arrangements in place to implement and support the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No. 225 of 1998).

Pharmacists should use their professional skills and competencies, and specialised knowledge, to encourage the rational and proper use of methadone and any other medicines the patient is taking. They should comply with all relevant laws, regulations and professional standards and ensure the patient is treated with courtesy, dignity, integrity and honesty. Pharmacists may be required to use their professional skills in decision-making, which may at times come into conflict with the demands of the patient.

Pharmacists, in particular superintendent and supervising pharmacists, should ensure that suitable controls and accountability mechanisms are in place, in order to appropriately control the supply of methadone and all other medicinal products which are known to have the potential for abuse and/or dependency.

5. Guidance

5.1 The Supply of Methadone for Opioid Dependence and the Provision of Associated Services to Patients

5.1.1 Initiating Methadone Services

Prior to commencing methadone treatment therapy services to patients, superintendent and supervising pharmacists must ensure that:

- the pharmacy premises, including the patient consultation area (or area where the consultation will occur), are appropriate³
- the pharmacy has all necessary equipment
- the provision of the service is covered by appropriate professional indemnity arrangements,
- there are adequate pharmacist staff available to allow for the appropriate supervision of all professional activities within the pharmacy and to fulfil all legal and professional requirements
- relevant policies and procedures are in place to ensure robust clinical governance and
- all pharmacists and other staff involved in providing the service are appropriately trained and competent to do so.

Pharmacists wishing to commence methadone services should contact the relevant Health Service Executive (HSE) liaison pharmacist, who will notify the retail pharmacy business (pharmacy) if a suitable patient presents for treatment and provide the pharmacist with additional relevant information. Prior to commencing supply, a pharmacy is required to be authorised by HSE addiction services to receive methadone from a wholesaler.

5.1.2 Registration of Patients

Every patient must be registered on the Central Treatment List, prior to commencing treatment. Each patient is registered with one specific, appropriately trained General Practitioner (GP) and one specific pharmacy. On registration, every patient is issued with a unique PH number and the pharmacy is issued with a treatment card containing this number, the patient's name, a photograph of the patient, a copy of the patient's signature and the name of the patient's GP and pharmacy. Cards are valid for a maximum of one year. They are the property of the pharmacy and should not be given to the patient.

³ Refer to *PSI Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses* and all other relevant information.

Pharmacists must ensure they only provide methadone services to patients registered to receive methadone from their pharmacy. Accordingly, all opioid dependent patients attending their pharmacy for methadone supplies must have a current valid drug treatment card. Pharmacists can check relevant information via the Central Treatment List (9am to 5pm, Monday to Friday, Phone: 01 6488640). Drug Treatment Cards should be stored safely and confidentially, on the pharmacy premises, and should be available and accessible, for reference, to all pharmacists practising in the pharmacy.

5.1.3 Medical Practitioners

GPs must undergo specific training in order to provide methadone services to patients. There are two levels of training, level one and level two; level one GPs may only treat stabilised patients, whereas level two GPs may initiate treatment and can provide services to a greater number of opioid dependant patients. A GP's level of training may be checked via the Central Treatment List.

5.1.4 New Patients

Prior to commencing the supply of methadone to an opioid-dependent patient, the supervising pharmacist should first satisfy himself/herself that the patient is a person in respect of whom a drug treatment card has been issued. The supervising pharmacist should then meet with the patient to discuss any issues the pharmacist or patient deems significant, including the patient's privacy, patient and pharmacist expectations from the service, providing the patient with relevant information and associated counselling. The confidential nature of the service should be explained to patients. If the pharmacy only dispenses methadone to patients at particular times, these times should be clearly communicated.

It is recommended that pharmacists put patient-pharmacy agreements in place regarding the parameters of the service. These agreements should be tailored to individual pharmacy requirements and specific patient needs. They should address the expectations of the patient and pharmacist, the risks associated with storing methadone incorrectly and with giving methadone to another person and all other items the pharmacist or patient may deem relevant.

5.1.5 Methadone Prescriptions

Methadone may only be supplied to a patient if it has been prescribed by their Methadone Protocol Scheme GP on the standard methadone prescription form. A copy of the methadone prescription form (as of November 2011) is appended to this guidance (**Appendix 1**). The prescription must comply with the prescription writing requirements for Schedule 2 controlled drugs, as provided for in regulation 13 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended).

The doctor must specify the patient's details including the PH number and the prescription details including the date, the preparation name, strength and form, the total amount of methadone prescribed in words and figures, the daily dose, details of the days on which methadone is to be dispensed and the days methadone is to be taken under the supervision of the pharmacist, along with the prescriber's signature and details. Individual methadone prescriptions for methadone treatment therapy should not be for more than seven days (eight days in exceptional circumstances, for example, to cover bank holidays).

Following the supply of methadone in instalments, each instalment should be entered on the prescription and when the full prescription has been dispensed, the total amount supplied must be entered in the controlled drugs register and the entry dated with the date of final supply. In addition, the pharmacist should stamp and sign the prescription which should also be signed by the patient following the final supply.

Methadone prescriptions must be forwarded to the HSE (this function is carried out by the HSE on behalf of the Minister for Health) no later than 14 days after the last day of the month in which the supply was completed.

5.1.6 Storage of Methadone

Methadone must be stored in a safe or cabinet which complies with the requirements of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) (as amended). The safe must be of sufficient capacity to store all stock of methadone and other Schedule 2 and 3 controlled drugs. Access to the safe should be controlled by the pharmacist and only the pharmacist or a person operating under the pharmacist's supervision should be permitted to access the safe.

5.1.7 Supply of Methadone

Pharmacists should be familiar with the Summary of Product Characteristics (SPC) for all methadone products they supply and copies should be readily accessible within the pharmacy.

Pharmacists must be cognisant of their obligations under regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). Prior to supplying methadone, a pharmacist should review the prescription, having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy, including screening for any potential drug therapy problems including interactions, incorrect dosage or duration of treatment and clinical abuse and/or misuse.

The directions of the prescribing practitioner should be followed when supplying methadone, including the dosing, supervision and instalment directions. Notwithstanding this, pharmacists must ensure any element of a prescription which is unclear or incorrect is clarified with the prescriber prior to its dispensing.

The ingestion of methadone under supervision must occur on the pharmacy premises and must be supervised by the pharmacist. This supervision should take place in the pharmacy's private patient consultation area (or another private designated area). In addition, the pharmacist should ascertain if the patient is fit to consume their dose and after consumption should ensure the patient has consumed their dose, either by talking to the patient or by offering the patient a drink of water.

Pharmacists should be aware that manufacturer's bottles contain an overage and 'take-away' doses of methadone should never be supplied in these bottles or other glass bottles. They should be packed in unbreakable plastic bottles, fitted with a child resistant cap. For certain patients, e.g. those whose dose has recently changed, individual doses are the safer option. If patients are provided with a bottle containing several doses, a measure should be given. The suitability of patients for multidose dispensing should be discussed with the prescribing GP, as appropriate. Patients should be informed of the importance of returning any remaining methadone to the pharmacy for safe disposal and should also be advised how to dispose of empty bottles safely.

All doses should be measured and double checked prior to dispensing and all supplies must be appropriately labelled.

Pharmacists should communicate any concerns about a patient to the prescriber, for example, if a patient misses a dose or if the patient appears to be under the influence of other drugs or alcohol. Pharmacists should be aware that if a patient has missed three or more doses their tolerance may be reduced and there is a risk of accidental overdose if the patient's full dose is dispensed. If the prescriber alters a dose a new prescription must be received which specifies the new dose.

5.1.8 Patient Counselling

Pharmacists must ensure each patient has sufficient information and advice on the proper use and storage of the product, and must offer to discuss all matters that the pharmacist in their professional judgement deems significant, as per their legal and professional obligations under regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).

Patients should be provided, at a minimum, with general information about methadone, including directions of use, any common side effects, the action to be taken if a dose is missed, interactions with alcohol and other drugs, e.g. benzodiazepines, cautionary notices about driving or operating heavy machinery, methods for safe disposal and the danger of an opioid-intolerant person ingesting methadone. In addition, pharmacists should be cognisant of patients' wider medical and healthcare needs and provide holistic pharmaceutical care to patients.

Patients should be encouraged to attend the pharmacy at the same time each day and the pharmacist must be available and offer to discuss any relevant issues with the patient, at each dispensing. Pharmacists should ensure that in instances where they are unable to provide services to a patient, they take reasonable action to ensure the services are provided and the patient's care is not jeopardised. In such circumstances, the relevant HSE liaison pharmacist should be contacted so an alternative service can be provided.

5.1.9 Multidisciplinary Patient Care

The supervising pharmacist and any other relevant pharmacist should establish a relationship with patients' medical practitioners and any other healthcare professionals involved in patients' care and regularly communicate with and/or meet these healthcare professionals. These communications/meetings should be a forum to discuss patients' care and treatment and any issues which the pharmacist or medical practitioner, in their professional judgement, deems appropriate. The primary aim should be to ensure patients receive an appropriate standard of care.

Interdisciplinary communication and continuity of care are particularly important for patients transitioning between environments, for example, patients transferring between drug treatment centres, hospitals, prisons and the community.

In addition, pharmacists should communicate relevant issues to their HSE liaison pharmacist and/ or GP coordinator, as appropriate.

5.1.10 Vaccination

All staff members providing services to opioid-dependant patients should be protected against Hepatitis B. The HSE's free hepatitis screening and vaccination scheme is available to all staff providing services within the Methadone Protocol Scheme and the HSE addiction services should be contacted if further information on this scheme is required.

6. Supplying Methadone to Medical Practitioners

In certain circumstances, a medical practitioner may request a supply of methadone for administration to patients under his/her care. In such circumstances, they are required to provide a written requisition to the pharmacist, as per the requirements for supplying a Schedule 2 controlled drug to a practitioner. Article 12 of the Misuse of Drugs Regulations 1988 (as amended) specifies the format of the requisition to be provided in such circumstances. Methadone may only be supplied to a practitioner if it has been requisitioned on the standard methadone prescription form and, as with

methadone prescriptions, requisitions must be forwarded to the HSE no later than 14 days after the last day of the month in which the supply was completed.

A pharmacist who supplies methadone on foot of a requisition must satisfy himself/herself, in so far as is possible, that the medication will be used appropriately, i.e. to treat patients under the practitioner's care.

7. Policies, Procedures, Training and Records

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of the sale and supply of methadone and the provision of associated services. All policies and procedures should comply with legislation, the Code of Conduct for pharmacists, the Methadone Protocol Scheme, this guidance and all other relevant guidance. There should be policies, procedures and/or protocols in place which address:

- new patients attending the pharmacy
- pharmacy-patient agreements
- dispensing and supplying methadone, including the identification of patients, preparation of doses, double checking, supervision of consumption, patient records etc.
- counselling patients
- the disposal of waste, including clinical, sharp, medicinal product and confidential waste
- maintaining confidentiality throughout the process
- interdisciplinary issues, including multi-disciplinary reviews, routine interactions and the continuity of patient care
- the management of the spillage of methadone and body fluids
- minimising the risk of disease transmission, including Hepatitis B vaccination of pharmacy staff

All relevant policies and procedures already in existence within the pharmacy, i.e. sourcing, storage, disposal⁴, controlled drug record keeping and patient consultation area procedures etc., should be reviewed and updated as appropriate to incorporate any additional requirements, and cross-referenced with the methadone policies and procedures as necessary.

In addition, pharmacies should have an error and incident management system for recording and addressing errors and/or near misses and for monitoring all incidents and complaints. The procedures in place should ensure open communication with patients and continuous quality improvement to reduce the likelihood of recurrence.

Superintendent and supervising pharmacists should ensure all pharmacists practising in the pharmacy, including those providing infrequent or occasional cover, and all other relevant staff are trained in the pharmacy's policies and procedures and training records should be maintained.

Every pharmacy should maintain a contact list with the contact details for patients, medical practitioners, the HSE liaison pharmacist(s), the GP co-ordinator(s) and all other relevant contacts.

All legislatively required records, including invoices, copies of prescriptions and the controlled drugs register must be retained for two years. The superintendent pharmacist may consider it appropriate to maintain records beyond a period of two years, as such records may be required for legal, insurance or other purposes at some time in the future.

⁴ The requirements for sourcing, storing and disposing of Schedule 2 controlled drugs are set out in the *PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business*.

There should be a system in place whereby all pharmacists maintain a record of relevant information and interactions pertaining to opioid-dependant patients, including patient-pharmacy agreements and records of all inter-professional reviews and other contact with prescribers.

Pharmacists should be familiar with all relevant legislation, PSI guidance and HSE guidance and should be familiar with, and trained in, the pharmacies policies and procedures. Pharmacists should also be familiar with the contents of the following reports and reviews:

- Report of the Methadone Treatment Services Review Group 1997 (Department of Health and Children)
- Review of the Methadone Treatment Protocol 2005 (Department of Health and Children)
- The Introduction of the Opioid Treatment Protocol (External Review of the Methadone Treatment Protocol) 2010 (HSE)

7.1 Enquiries

Persons enquiring about treatment for drug addiction should be referred in the first instance to their GP or a drug treatment clinic. In addition, addiction services employ outreach workers who are in contact with drug users in the community and can facilitate introduction to treatment, or patients can be referred to the HSE Drugs/ HIV Helpline or www.drugs.ie. Information on drug treatment clinics and outreach workers is available from HSE addiction services.

8. Supply of Methadone in Hospitals

The provisions of the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No. 225 of 1998) do not apply to methadone prescriptions issued in a hospital for administration to a patient in the hospital or, in exceptional circumstances, for supply to a patient who has attended the hospital for the treatment of opioid dependence or as an inpatient who is opioid dependent. Pharmacists supplying methadone in hospitals must be cognisant of all other requirements which must still be fulfilled in order to ensure compliance with legal and professional obligations and should ensure appropriate arrangements are in place for patients continuing treatment who are transitioning back into primary care.

9. Supply of Methadone other than for Opioid Dependence

Methadone may be used for the relief of severe pain in conditions where morphine may be a reasonable alternative, such as severe cancer pain. Pharmacists should ensure they are familiar with the SPCs, including the licensed indications, for all methadone products they supply and copies should be readily accessible within the pharmacy.

The provisions of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) and the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No. 225 of 1998) still apply. Methadone must still be prescribed on the standard methadone prescription form and the pharmacy must be authorised by the Department of Health to receive methadone from a wholesaler. The form of methadone (liquid, capsules or injection) and the strength of the preparation to be dispensed must be stated and the prescription must comply with controlled drug prescription writing requirements.

However, the requirement that a patient is on the Central Treatment List and has been issued a drug treatment card does not apply, provided the prescription is issued by a medical consultant, or by a registered medical practitioner, following initiation by a medical consultant, and the consultant's name and address are included on the prescription. In addition, in these cases, methadone can be prescribed for up to one month, as the rule that individual methadone prescriptions should not be for more than seven days does not apply.

Some methadone products may be 'exempt medicinal products'⁵ (i.e. unauthorised/unlicensed medicinal products), in which case, pharmacists must be cognisant of the need to fulfil the additional requirements relating to such medicinal products.

Pharmacists should discuss patients' care and treatment with all relevant health care professionals, e.g. medical practitioners or pharmacists in other care settings, both when treatment is initiated and at appropriate intervals thereafter. Such discussions should highlight any issues which the pharmacist in their professional judgement deems appropriate. The primary aim should be to ensure patients receive an appropriate standard of care at all times, including when transitioning between environments, for example, when transferring from a hospital to community setting.

Pharmacists supplying methadone and providing services to patients should be sufficiently competent in the management of chronic severe pain, familiar with all relevant clinical information and aware of the potential for dependence, abuse or misuse. They should communicate all relevant information to patients, or their carers, as appropriate.

All relevant legislation is available via the PSI website www.thePSI.ie or via www.irishstatutebook.ie.

***Pharmaceutical Society of Ireland
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⁵ An 'Exempt Medicinal Product' is defined in the Medicinal Products (Control of Manufacture) Regulations 2007 as a medicinal product to which paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007, or any equivalent legislation in any EEA State other than the State, applies.

Appendix 1

METHADONE PRESCRIPTION FORM

PHARMACY SEQUENCE NO. SERIAL NO. 773

PATIENT DETAILS ADDRESS

SURNAME PATIENT'S AGE IF UNDER 16

FIRST NAME TREATMENT CARD NO.

PRESCRIPTION DETAILS DRUG NAME, FORM AND STRENGTH

DATE PRESCRIBED

FROM	TO	DOSAGE (mls PER DAY)	NO. OF DAYS AT DOSE	TOTAL (mls) (IN FIGURES)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

TOTAL (mls) IN WORDS
(NOT MORE THAN 7 DAYS SUPPLY SHOULD BE PRESCRIBED EXCEPT IN EXCEPTIONAL CIRCUMSTANCES)

DOCTOR'S SIGNATURE

DOCTOR'S NO.

DOCTOR'S NAME, ADDRESS AND TELEPHONE NUMBER OR STAMP

INSTALLMENT

INTERVAL

DAILY ☐

ON SAT. ☐

MON TUES WED THURS FRI SAT SUN

DISPENSATION INSTRUCTIONS

*YES NO

ADVISED ☐

SUNDAY TO SATURDAY ☐

EVERYDAY ☐

OTHER (TICK) ☐

MON TUES WED THURS FRI SAT SUN

*ONLY WITH PRIOR AGREEMENT OF PHARMACIST

PHARMACY SECTION

PHARMACY GMS ☐ NO. OF PHARMACY NAME & ADDRESS STAMP

DRUG CODE QUANTITY (mls) SUPERVISED DAYS

DATE DISPENSED QUANTITY PHARMACIST'S INITIALS

I VERIFY THAT I HAVE DISPENSED THE ITEM(S) SPECIFIED HEREON

PHARMACIST'S SIGNATURE

I VERIFY THAT I HAVE RECEIVED THE ITEM(S) SPECIFIED HEREON

SIGNATURE

OF PATIENT OR PATIENT'S REPRESENTATIVE

TO BE COMPLETED IN THE CASE OF NON-OPIATE DEPENDENT PERSON

NAME AND ADDRESS OF INITIATING CONSULTANT

HOSPITAL MEDICAL CARD NO.

HEALTH SERVICES SCHEME

GMS ☐ EEA ☐ OTHER ☐

This prescription form is issued on behalf of the Minister for Health and Children for the purposes of the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998.