

GUIDANCE

Licencing arrangements for prescribing, supplying and administering diamorphine, cocaine and dipipanone for the treatment of drug misuse and addiction.

Under the Misuse of Drugs (Supply to Addicts) Regulations 1997, the Scottish Ministers have the power to grant licences to allow registered medical practitioners to prescribe, supply and administer (or authorise the supply and administration) of Cocaine, Diamorphine and Dipipanone for the treatment of drug misuse.

Prior to applying to Scottish Government for a prescribing licence, the applicant must also ensure that they already have a licence in place for the specific premises in which the prescribing, supply and administration of these controlled drugs will take place. This 'premises' licence must be applied for through the UK Government's Drug's and Firearms Licencing Unit at the Home Office.

Access to the application form and associated information can be found at the UK Government website - <https://www.gov.uk/government/publications/domestic-controlled-drug-licensing-in-healthcare-settings>

Further information can also be found here - <https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>

Policy Context

The Scottish Government recognises the need to provide a range of treatment options for those who are at risk as a result of their drug use. The Scottish Government does not promote any one treatment over another but insists that any treatment is:

- i. evidence based;
- ii. agreed and reviewed regularly with the patient;
- iii. part of a broader package of care, treatment and recovery;
- iv. in line with good practice as set out by the 'UK Guidelines on Clinical Management; Drug Misuse and Dependence (2017)'.

Applying for a Prescribing Licence to Scottish Government

Where registered medical practitioners consider that prescribing Cocaine, Diamorphine or Dipipanone may be an appropriate option for a patient/patients then they must apply to the Scottish Government for a prescribing licence

Applicants must, as a minimum requirement for the licence, be:

- a) **fully registered with the General Medical Council and licenced to practice;**
- b) **employed by a Health Board or providing services on behalf of a Health Board; and**
- c) **either:**
 - i. **Consultants with a Certificate of Completion of Training (CCT) in Psychiatry and a specialism and experience in managing substance misuse; or**

ii. **Generalists who have completed the Royal College of General Practitioners (RCGP) Certificate in the Management of Substance Misuse (Parts 1 and 2) or equivalent and with experience in managing substance misuse.**

Applicants should make their local Health Board aware of their intention to apply. Each application must be supported by the prescriber's local Health Board. It is the responsibility of the applicant to ensure that all information provided in sections 1 and 2 of the application form are accurate. The Health Board will also be held responsible for ensuring the details contained in the application are accurate and that all practice is undertaken in adherence with prescribing guidelines and clinical guidance. The fully completed application must be authorised by the Health Board's Medical Director before submission to the Scottish Government.

The application form will be reviewed by the Scottish Government's Chief Medical Officer (or an appointed deputy), Chief Pharmaceutical Officer (or an appointed deputy) and Substance Misuse Unit. Final authorisation and approval will be made by the Chief Medical Officer (or an appointed deputy).

This application process is subject to regular review and amendment by the Scottish Government.

Completing the Application Form

Section	Completed By	Forward to
1 & 2	Applicant	Controlled Drugs Accountable Officer (CDAO) of the NHS Board
3	NHS Board CDAO	Medical Director of NHS Board
4	NHS Board Medical Director	Substance Misuse Unit at St Andrews House (see below)

Section 1 and Section 2 of the application form must be completed by the individual medical practitioner (the "applicant"). The form should then be forwarded to the Controlled Drugs Accountable Officer (CDAO) of the appropriate Health Board.

Section 3 must be completed by the CDAO who should consider the accuracy of the application. The form should then be forwarded to the Medical Director to complete.

Section 4 should be completed by the Medical Director on behalf of the Health Board. By signing section 4, the Medical Director undertakes to ensure that the licensee will be provided with appropriate guidance and supervision in adhering to the terms of the licence. The Medical Director is also confirming that the information provided on the licence application form is correct and accurate and that the applicant:

- meets the minimum requirements set out above; and
- in the Medical Director's view, is able to fully meet the clinical guidelines for the treatment of drug addiction.

By signing the form the applicant also confirms that the licence will only be used

- a) by a medical practitioner who is practising in Scotland; and
- b) in connection with patients residing and being treated in Scotland.

Completed application forms must be clearly legible. Applications that are not legible will not be processed and will be returned to the applicant.

Monitoring and Reporting Arrangements

In order to assess the impact of this licencing arrangement and its effectiveness, the Scottish Government requires each licensed prescriber to record specific information as a condition of licence (as outlined below). This information may be requested for future use/analysis by the Scottish Government and/or Information Services Division. It is the licensed prescriber's responsibility to ensure the accuracy of this information.

Licensed prescribers should make this information available to the sponsoring Health Board / service manager. This information will be used by Health Boards / the service manager (or nominated colleague) to inform a yearly report that should be provided to the Scottish Government Substance Misuse Unit by 31 May (reporting on the preceding financial year) to help assess the overall outcomes and effectiveness of this policy intervention.

Information to be Recorded by Licensed Prescribers

The following information should be recorded by each licensed prescriber (as a minimum), in the event it is required for future use / analysis by Scottish Government and/or Information Services Division:

1. The total number of patients who have been prescribed, supplied or administered diamorphine.
2. The total number of patients who have been prescribed, supplied or administered cocaine.
3. The total number of patients who have been prescribed, supplied or administered dipipanone.
4. Per patient (some may not be applicable depending on the services provided):
 - CHI number
 - The prescribed dose
 - The duration for each dose
 - Total number of doses or days or prescriptions – onsite supervised administration
 - Total quantity - onsite supervised administration
5. The number of individuals on each of the possible combinations of drugs and the duration of the combination.
6. Total cost of drugs prescribed
7. Adverse event information (overdose, death, etc) – outline any events and action taken

Yearly Report to the Scottish Government

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Information collected by licensed prescribers should be used to inform a yearly 'overview' report of the service that outlines the impact the use of this licence has had. This should include information drawing on items 1-3 and 5-7 from the above list. It should also outline what challenges have been faced and what, if any, changes are planned for the following year.

It is the responsibility of the sponsoring Health Board and the service manager (or nominated colleague) to ensure that this report is provided to the Scottish Government Substance Misuse Unit by 31 May each year.

The data collection and reporting arrangements will be reviewed on a yearly basis to ensure relevant data is being captured. In the event of any changes, the Health Board, service managers and the licensed prescribers will be informed by the Scottish Government.

The Health Board will be responsible for ensuring that appropriate monitoring and reporting arrangements are in place to ensure that:

- the terms of the licence are properly adhered to;
- relevant data governance arrangements are in place; and
- that monitoring and reporting information is recorded, and provided to Scottish Government as detailed above.

As part of the application process, Scottish Government may also request information from service providers/Health Boards that clearly detail the data/information the service intend to collect as part of their local monitoring and reporting arrangements.

Terms and conditions of the Licence

The licence allows registered medical practitioners to prescribe, supply and administer, or authorise the administration or supply of Cocaine, Diamorphine or Dipipanone in the treatment of drug misuse and addiction only. The licence applies only to the medical practitioner who has applied and been approved for the licence and is only valid within the premises approved by the licence. Should the medical professional move premises, his/her licence becomes void and a new licence application will be required. In the event the licensed prescriber permanently leaves the service, they will be required to inform their CDAO and Medical Director, who should then inform Scottish Government.

The licensed prescriber must notify Scottish Government in writing of any change to details provided as part of the application process, consideration will then be given as to whether details can be updated or whether a new application will be required.

Licence approvals will be for a period of 36 months (3 years). If a licensee wishes to extend the approval beyond 36 months they will be required to submit a new application. It is the responsibility of the licensed prescriber to ensure that licences are valid and renewed in a timely fashion.

Licensed Prescribers

Under the terms of the licence, the licensed prescriber is required to:

- be fully registered with the General Medical Council and licenced to practice;
- be treating a patient residing in Scotland;
- be treating patients at premises, located in Scotland, with a Home Office licence;
- treat patients in accordance with the 'UK Guidelines on Clinical Management: Drug misuse and dependence'.

Health Board

Under the terms of the licence Health Boards are responsible for:

- ensuring that all practice is undertaken in adherence with prescribing guidelines and clinical guidance;
- maintaining an overview of valid licences;
- ensuring that a suitable number of individuals have licences at each premises to ensure the continued provision of the service;
- ensuring that appropriate monitoring and reporting arrangements are in place;
- Ensuring a yearly report is provided to Scottish Government;
- Reporting of any 'exceptional' events/issues.

CDAO

Under the terms of the licence CDAOs are responsible for:

- ensuring that the premises / service has effective systems in place for the safe and secure management of controlled drugs and appropriate prescribing practice;

Application Decision

Decisions on applications for licenses will be made in accordance with this policy and procedure.

Applications are considered on a case by case basis. As the appropriate authority, it is the Scottish Government's decision whether or not to issue a licence. The time taken to consider an application may vary and will depend on:

- If additional information is required;
- Whether a licence or approval is required from another regulatory body (e.g. Home Office) before we issue a licence;
- If we need to visit your premises.

Where an application has been successful, the Chief Medical Officer or an appointed Deputy will notify the applicant, CDAO and Medical Director of the Health Board in writing. This letter will provide the necessary authority for the applicant to prescribe, supply and administer (or authorise the supply and administration of) Diamorphine, Cocaine and Dipipanone for the treatment of drug misuse and addiction. The Scottish Government will maintain a database of all such licences. The letter issued and the entry on the Scottish Government database will constitute the licence – no

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other paper certificate or record of the licence will be issued to the licensed prescriber.

Where an application has been unsuccessful the Chief Medical Officer will notify the applicant, CDAO and Medical Director of the Health Board in writing. The letter will provide reasons for the decision along with details of the applicant's right of appeal.

Right to Appeal

Where an application for a licence has been declined the applicant has the right to appeal. Should an applicant wish to appeal he/she should submit an appeal in writing. Appeals should be submitted to the Scottish Government within 28 days of receipt of the decision letter. Medical Directors and CDAOs should consider the content of the appeal in the first instance and if supported, the appeal should be sent to the Drugs Policy Unit within Scottish Government.

The appeals process will be co-ordinated by a member of the Scottish Government Directorate for Population Health Management Team and will involve a clinical specialist in the Directorate General for Health and Social Care or Chief Medical Officer's Office (who was not involved in the original decision). The Substance Misuse Unit will provide the Health Board with a decision on the appeal within 28 days of its receipt. This decision is final, with no subsequent right of appeal.

Removal of Licence Approval

Scottish Ministers reserve the right to remove licence approvals from medical practitioners in situations where the applicant fails to meet the conditions attached to the licence (as outlined in this guidance), including where the Scottish Government becomes aware that the licensed prescriber is carrying out licensed prescribing, supply or administration of diamorphine, cocaine or dipipanone (or authorising the same):

- a) from premises which do not meet the standards required by this guidance, or by a premises licence issued by the Home Office; or
- b) on behalf of a Health Board which has failed to meet the standards required of it under this guidance.

Anyone who has concerns about how a practitioner is using their licence should report the matter to the relevant Health Board or to the Substance Misuse Unit of the Scottish Government.

In order to remove a licence the Scottish Government will write to the licensed prescriber, the Medical Director and CDAO of the Health Board advising that the licence has been revoked. The letter will provide the reasons why the decision has been taken.

Medical practitioners have the right to appeal against this decision. The appeals process is the same as that for appealing against a decision not to grant a licence.

Medical practitioners whose licence has been revoked will no longer have the power to prescribe, supply, administer, or authorise the administration or supply of Cocaine,

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Diamorphine and Dipipanone for the treatment of drug misuse and addiction and should cease doing so immediately. Continuing without licence approval is a criminal offence which can result in a custodial sentence.

Obtaining an application form

A copy of the application form is attached to this guidance. Application forms can also be downloaded from the Scottish Government's website:

<https://www.gov.scot/publications/licensing-to-prescribe-diamorphine-cocaine-and-dipipanone-guidance/>

Hard copies of the application form can be obtained from the Substance Misuse Unit of the Scottish Government by telephone or e-mail:

Telephone: 0131 244 5047

Email: adpnewsletter@gov.scot

Submitting the application form

Fully completed application forms should be returned by the Health Board to:

Substance Misuse Unit, Scottish Government, St. Andrew's House, Regent Road
Edinburgh. EH1 3DG.