Dear Colleague,

**LICENSING ARRANGEMENTS FOR PRESCRIBING, SUPPLYING AND ADMINISTERING DIAMORPHINE, COCAINE AND DIPIPANONE FOR THE TREATMENT OF DRUG MISUSE AND ADDICTION**

This guidance informs you of changes to the licensing arrangements for prescribing, supplying and administering Diamorphine, Cocaine and Dipipanone for the treatment of drug misuse and addiction. These changes only provide for a transfer of power from the Home Office to the Scottish Government and do not in any way reflect a shift in policy or a promotion of any treatment option over another. The arrangements apply only to applications for licenses from doctors with accredited specialist expertise in managing substance misuse registered with the General Medical Council and does not provide for independent or supplementary prescribers.

**Purpose**

Currently, the provision of licences to allow doctors to prescribe, supply and administer (or authorise the supply and administration) Cocaine, Diamorphine and Dipipanone for the treatment of drug misuse and addiction is a matter for the Home Office. It is a reserved matter under the terms of the Misuse of Drugs Act 1971 and the Misuse of Drugs (Supply to Addicts) Regulations 1997.

One of the Calman Commission recommendations was to devolve the powers for issuing licenses to Scottish Ministers as they found there was “scope for executive devolution of the powers of UK Ministers to allow some controlled drugs to be legally prescribed by doctors (and therefore held and used legally) for the purpose of treating addiction.” The recommendation was taken forward in the Scotland Bill and will now be enabled by the Scotland Act 2012 with the relevant section planned for commencement on 31 October 2012.
Guidance has been developed which provides details of how the new arrangements for applying for a licence will operate in Scotland and this is attached at Annex A.

**Action**

NHS Boards and Special Health Boards should ensure that they introduce licensing arrangements for prescribing, supplying and administering Diamorphine, Cocaine and Dipipanone for the treatment of drug misuse and addiction, in hours and out of hours, in accordance with the provisions outlined in this letter.

This Chief Executive Letter (CEL) can be obtained on line at [www.sehd.scot.nhs.uk](http://www.sehd.scot.nhs.uk)

Yours sincerely

*Bill Scott*  
*Harry Burns*  
*Gillian Russell*

PROFESSOR BILL SCOTT  
Chief Pharmaceutical Officer  
SIR HARRY BURNS  
Chief Medical Officer  
GILLIAN RUSSELL  
Deputy Director  
DG Learning & Justice
ANNEX A

LICENSING ARRANGEMENTS FOR PRESCRIBING, SUPPLYING AND ADMINISTERING DIAMORPHINE, COCAINE AND DIPIPANONE FOR THE TREATMENT OF DRUG MISUSE AND ADDICTION

Introduction

This guidance sets out a change to the current arrangements for applying for a licence to enable the prescribing, supplying and administering of Diamorphine, Cocaine and Dipipanone for the treatment of drug misuse and addiction. Currently, applications for a licence are made directly to the Home Office under the terms of the Misuse of Drugs Act 1971 and the Misuse of Drugs (Supply to Addicts) Regulations 1997. Legislative changes coming into force from 31 October 2012, however, mean that licences will be authorised by Scottish Ministers under the terms of the Scotland Act 2012. The legislative changes allow for a transfer of power for licensing from the Home Office to Scottish Ministers and do not in any way reflect a shift in policy or a promotion of any treatment option over another.

This paper provides guidance by setting out the policy framework and the arrangements which have been put in place for applying for a license. It also explains how applications will be processed and introduces monitoring arrangements.

Policy context

The prescription of Diamorphine, Dipipanone and Cocaine for the treatment of drug misuse and addiction has been allowed since the assent of the Misuse of Drugs Act 1971. This Act and all associated Acts and amendments continue to be reserved to the UK Parliament. The Calman Commission recommended that the power to licence Doctors to prescribe certain controlled drugs (Cocaine, Diamorphine and Dipipanone) be transferred to Scotland. The Scotland Act 2012 amended the Misuse of Drugs Act 1971 and the associated Misuse of Drugs (Supply to Addicts) Regulations 1997 to enable the change to take place.

Scotland has a long-running and serious drug problem. In response to this the Scottish government launched the Road to Recovery: A New Strategy for Tackling Scotland’s Drug Problem. This strategy is focussed on recovery but also provides for prevention, treatment and rehabilitation, education, enforcement and protection of children. The Scottish Government does not promote any one treatment over any other but insists that any treatment is evidence based, agreed and reviewed regularly with the patient and is part of a broader package of care, treatment and recovery. Any treatment must be closely supervised in line with good practice as set out by the UK guidelines on Clinical Management: Drug misuse and dependence published in 2007. The Scottish Government promoted the guidelines in the national strategy the Road to Recovery. These guidelines provide guidance on the treatment of drug misuse in the UK.
Where Doctors consider that prescribing Cocaine, Diamorphine or Dipipanone may be an appropriate option for a patient then they must apply for a licence to authorise them to use this option within national/local protocols.

Applying for a Licence

Applicants should apply to their local Health Board. The Health Board will require to support each application and will have responsibility for ensuring the details contained in the application are accurate. Health Boards will also have an ongoing role to ensure that the in hours service being supplied by the licence holder is necessary and effective, and includes appropriate protocols for out of hours cover. Final authorisation and approval of an application will be given by the Scottish Governments Chief Medical Officer or an appointed deputy.

To apply for a licence, applicants must complete section 1 and 2 of the application form. The form should then be forwarded to the Controlled Drugs Accountable Officer (CDAO) of the appropriate NHS Board. Section 3 should be completed by the CDAO who should consider the accuracy of the application and also feed in any concerns which may have previously been raised with them - for example via the Accountable Officers Network. Once signed or otherwise the form should then be forwarded to the Medical Director who should complete section 4 on behalf of the 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 is:

- registered with the General Medical Council
- employed by the Health Board or providing services on behalf of the Health Board
- able to fully meet the clinical guidelines for the treatment of drug addiction
- practising within a managed service

Signing the form also confirms that the licence will only be used

- by a doctor who is practising in Scotland; and
- in connection with patients residing and being treated in Scotland.

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; and
- that treatment outcomes are monitored and reported upon and that this information is provided to the Scottish Government on an annual basis.

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1 Department of Health (England), Scottish Government, Welsh Assembly and Northern Ireland Executive, Drug Misuse and Dependence, UK guidelines on Clinical management, September, 2007.
Completed application forms must be clearly legible. Applications that are not legible will not be processed and will be returned to the applicant.

**Terms and conditions of the Licence**

The licence allows Doctors to prescribe, supply and administer, or authorise the supply or administration of Cocaine, Diamorphine or Dipipanone in the treatment of drug misuse and addiction only. The licence applies only to the Doctor who has applied and been approved for the licence and is only valid within the premises approved by the licence. Should a Doctor move premises, his/her licence becomes void and a new licence application will be required.

Any change in details must be notified in writing to the Health Board who will consider whether details can be updated or whether a new application will be required. Licence approvals will be for 24 month periods. If a licensee wishes to extend the approval beyond 24 months they will be required to submit a new application.

Before applying for a licence a Doctor is required to:

- be registered with the General Medical Council;
- be treating a patient residing in Scotland;
- be treating patients at suitable premises\(^2\) which are located in Scotland;
- treat patients in accordance with the *UK Guidelines on Clinical Management: Drug misuse and dependence*.

**Application Decisions**

Decisions on applications for licenses will be made in accordance with this policy and procedure. Where an application has been successful, the Chief Medical Officer or an appointed Deputy will notify the CDAO and Medical Director of the Health Board in writing. It will be or the Health Board to notify the applicant on the outcome of the application. The letter will provide the necessary authority for the applicant to prescribe, supply and administer Diamorphine, Cocaine and Dipipanone for the treatment of drug misuse and addiction. The Scottish Government will maintain a database of all such approvals. No actual licenses will be issued which is in line with current Home Office arrangements.

Where an application has been unsuccessful the Chief Medical Officer will notify the 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. It will be for the Health Board to notify the applicant on the outcome of the application.

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\(^2\) A suitable treatment facility is as described in the Department of Health (England), Scottish Government, Welsh Assembly and Northern Ireland Executive, Drug Misuse and dependence, UK guidelines on Clinical management, September, 2007.
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 Medical Director and CDAO of the Health Board 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 Justice Directorate management team and will involve a clinical specialist in the Directorate General for Health and Social Care who was not involved in the original decision. The Drugs Policy 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 Approvals

Scottish Ministers reserve the right to remove licence approvals from Doctors.

Anyone who has concerns about how a Doctor is using their licence should report the matter to the Drugs Policy Unit of the Scottish Government.

In order to remove a licence approval the Scottish Government will write to the Medical Director and CDAO of the Health Board advising that the licence approval has been revoked. The letter will provide the reasons why the decision has been taken. The Scottish Government may also advise the General Medical Council if appropriate.

Doctors 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.

Doctors whose licence approval has been revoked will no longer have the power to prescribe, supply, administer, or authorise the supply or administration of Cocaine, Diamorphine and Dipipanone for the treatment of drug misuse and addiction and should cease doing so without delay. To continue to prescribe, supply and administer or authorise the supply or administration of Cocaine, Diamorphine and Dipipanone for the treatment of drug misuse and addiction without licence approval is a criminal offence which can result in a custodial sentence.

Current holders of a licence issued by the Home Office

Doctors who currently hold a licence issued previously by the Home Office and need the licence approval to continue will be required to submit a new application under the terms of the arrangements in Scotland. Home Office licenses will only continue to be valid until 31 December 2012. This transitional period will allow sufficient time for doctors to apply for a new licence under Scottish Arrangements.
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 Drug Policy Unit website:


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

Telephone: 0131-556-8400

Email: ceu@scotland.gsi.gov.uk

Minicom: 0131-244-1829 (service for the deaf)

Submitting the application form

Fully completed application forms and a covering letter on headed notepaper supporting the application should be returned by the Health Board to:

Drugs Policy Unit
Scottish Government
St. Andrew’s House
Regent Road
Edinburgh
EH1 3DG
Monitoring and Reporting

The Scottish Government requires to assess the impact of licensing and to assess the effectiveness of the policy. In order to assess the impact of licensing, Doctors with a licence should record and report - on an annual\(^3\) basis:

- **the total number** of patients who have been prescribed, supplied or administered *Diamorphine* and for each individual:
  - the dose of the drug used
  - the duration of treatment

- **the total number** of patients who have been prescribed, supplied or administered *Cocaine* and for each individual:
  - the dose of the drug used
  - the duration of treatment

- **the total number** of patients who have been prescribed, supplied or administered *Dipipanone* and for each individual:
  - the dose of the drug used
  - the duration of treatment

- **the total number** of out of hours requests, reasons for them and outcomes

Monitoring information should be returned by no later than 30 April each year to:

Drugs Policy Unit  
Scottish Government  
St. Andrew’s House  
Regent Road  
Edinburgh  
EH1 3DG

**Review**

This policy and procedure will be reviewed in 12 months and thereafter every three years.

\(^3\) On an annual basis means the financial year from 5\(^{th}\) April.
Application for a licence to prescribe, administer, supply or authorise the administration or supply of Cocaine, Diamorphine and Dipipanone for the treatment of drug misuse and addiction under the Misuse of Drugs Act, 1971 and the Misuse of Drugs (Supply to Addicts) Regulations, 1997, as amended by the Scotland Act, 2012.

This application should be completed in full.

It can be typed or completed by hand. It must be legible and must be signed by hand where a signature is required.

**SECTION 1 (to be completed by the applicant)**

<table>
<thead>
<tr>
<th>Applicant details</th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
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<td><strong>Forename</strong></td>
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<tr>
<td><strong>Surname</strong></td>
</tr>
<tr>
<td><strong>Job Title</strong></td>
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<tr>
<td><strong>General Medical Council Registration Number</strong></td>
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<tr>
<td><strong>Date fully registered with General Medical Council</strong></td>
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<tr>
<td><strong>Are you currently fully registered with the General Medical Council</strong></td>
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<tr>
<td><strong>Do you have a relevant accredited specialist training and competency in drugs misuse and if so what is it?</strong></td>
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<tr>
<th>Work place and employer</th>
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<tr>
<td><strong>Name, address and telephone number of applicant’s current workplace</strong></td>
</tr>
<tr>
<td><strong>Name of applicant’s current Health Board Area</strong></td>
</tr>
</tbody>
</table>
**Treatment premises and demand for services**

<table>
<thead>
<tr>
<th>Name(s), address(s) and telephone number(s) of treatment premises at which this licence will apply i.e. where the above drugs will be prescribed, supplied, administered or authorised.</th>
<th>Cocaine</th>
<th>Diamorphine</th>
<th>Dipipanone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please state the drugs that you wish a licence for</td>
<td>In-patients:</td>
<td>Out-patients:</td>
<td>In-patients and outpatients</td>
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<tr>
<td></td>
<td>-in hours</td>
<td>-in hours</td>
<td>-in hours</td>
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<tr>
<td></td>
<td>-out of hours</td>
<td>-out of hours</td>
<td>-out of hours</td>
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<tr>
<td>Please state whether you will be treating in-patients, out-patients or both and whether this will be in or out of hours. If you are treating neither then please specify who is to be treated and how on a separate sheet.</td>
<td>In-patients</td>
<td>Out-patients</td>
<td>Other – (as specified above).</td>
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<td>-in hours</td>
<td>-in hours</td>
<td>-in hours</td>
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<tr>
<td></td>
<td>-out of hours</td>
<td>-out of hours</td>
<td>-out of hours</td>
</tr>
<tr>
<td>Please state the approximate number of patients that you anticipate will be treated under the terms of this licence in the next 12 months.</td>
<td>Diamorphine only</td>
<td>Cocaine only</td>
<td>Dipipanone only</td>
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<tr>
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<td></td>
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<tr>
<td>Please state the approximate quantity of drugs that you anticipate being used under the terms of this licence on a monthly basis</td>
<td>Diamorphine</td>
<td>Cocaine</td>
<td>Dipipanone</td>
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</table>
The Scottish Government will require monitoring information from you on the operation of this licence. This will include numbers of patients treated, quantity of drugs used and duration.

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<tr>
<th>I agree to provide this information</th>
<th>I do not agree to provide this information</th>
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</table>

Have you previously been disciplined by your current or a previous employer, by the General Medical Council or by any other professional association?

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<th>Yes</th>
<th>No</th>
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Are you currently subject to any form of suspension, investigation or disciplinary action by a previous or current employer, by the General Medical Council or by any other professional association?

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<th>Yes</th>
<th>No</th>
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Do you have any previous or ongoing convictions?

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<th>Yes</th>
<th>No</th>
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If you have answered yes to any of the above three questions please provide further details below.

Please state any other factors which you consider should be taken into account in respect of this licence application?

**APPLICANTS DECLARATION**

By signing this application I confirm that I am registered with the General Medical Council and will be treating patients residing in Scotland at suitable premises which are located in Scotland. Treatment will be in accordance with the *UK Guidelines on Clinical Management: Drug misuse and dependence.*

I fully understand the licence allows me to prescribe, supply and administer, or authorise the supply or administration of Cocaine, Diamorphine or Dipipanone in the treatment of drug misuse and addiction only. The licence applies only to me and is only valid within the premises approved by the licence. I also understand that should I move premises, my licence becomes void and a new licence application will be
required.

I agree to informing my Health Board of any change in details.

I hereby declare that to the best of my knowledge and belief all of the particulars given in this application are correct.

Signed:--------------------------- Date:------------------------

Please note: Under Section 18(4)(a) of the Misuse of Drugs Act, 1971, it is an offence for any person to make a statement or to give any information which he/she knows to be false for the purpose of obtaining the issue of a licence or other authority under the Act.
SECTION 3
(to be completed by the Health Board Controlled Drug Accountable Officer)

Name of Health Board: ______________________________

I confirm that I have fully and properly checked the information contained in this application form and am content to recommend a licence be granted.

Title: ______  Forename: ___________________  Surname:____________________

Job Title:____________________

Address:........................................................................................................

....................................................................................................................

Telephone Number: ___________  E-mail address: __________________________

Signature: ________________  Date: ___________________

Note: Once completed the CDAO should forward the form to the Medical Director to complete section 4 below.
SECTION 4
(to be completed by the Medical Director on behalf of the NHS Board)

Nomination by Health Board

Name of Health Board: __________________________

I confirm that I have fully and properly checked the information contained on this application form.

I can therefore confirm that the details as provided:
(delete as appropriate) are correct and accurate / are not correct and accurate.

(delete as appropriate I support the application / I do not support the application.

Title: ______  Forename: __________________  Surname:____________________

Job Title:____________________

Address: ________________________________________

________________________________________________________________________

________________________________________________________________________

Telephone Number: ____________  E-mail address: __________________________

Signature: ____________  Date: ____________

Once completed the Health Board should return the application form to: Drugs Policy Unit, Scottish Government, St. Andrew’s House, Regent Road, Edinburgh, EH1 3DG.
## SECTION 5: Scottish Government Authorisation

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<th>Assessment of Drugs Policy Unit</th>
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<td>Drugs Policy Unit</td>
<td>This application is / is not supported</td>
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<td>Pharmacy Division</td>
<td>This application is / is not supported</td>
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<th>Assessment of Chief Medical Officer</th>
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<td>Chief Medical Officer</td>
<td>This application is / is not approved</td>
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<td>Signed: Date:</td>
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<th>Database Updated</th>
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