

# Memorandum of Understanding between the Home Office and the General Pharmaceutical Council

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## Introduction

The memorandum of understanding (MoU) outlines the basis of cooperation between the Home Office Drugs Licensing and Compliance Unit (DLCU) and the General Pharmaceutical Council (GPhC), and supports the GPhC's role as the principal regulator responsible for inspections of registered pharmacies.

The aims of this MoU are to:

- Ensure the safer management of controlled drugs in pharmacy settings, and reduce the risk of diversion
- Maintain patient safety and confidence in pharmacy services
- Support the sharing of intelligence and information
- Contribute to improving the regulatory oversight of pharmacy activities
- Create the potential for reducing the burden of inspection activities in pharmacies
- Define the circumstances in which the two organisations will act independently.

This MoU is a statement of principle; more detailed operational protocols and guidance will be developed, as these are required.

Although the DLCU and the GPhC agree to adhere to the contents of this MoU, it is not intended to be a legally binding document. It does not override the organisations' statutory responsibilities or functions, nor infringe the autonomy and accountability of the DLCU and the GPhC or their governing bodies.

Both organisations agree to abide by the Information Commissioners Office data sharing code of practice, and recognise their respective responsibilities as data controllers under the Data Protection Act 1998 and public bodies under the Freedom of Information Act 2000.

## Roles and responsibilities

The Home Office Drugs Licensing and Compliance Unit (DLCU) is the UK Competent Authority for the licensing of individuals or organisations to produce, possess, supply or manufacture Controlled Drugs, defined in accordance with the Misuse of Drugs Act 1971 and its associated Regulations 2001. It also has responsibility for Drug Precursor Chemical licensing and registration, and manages all imports and exports of Controlled Drugs or Precursor Chemicals to or from the UK. It operates a risk-based and proportionate compliance regime on a full-cost recovery model. Domestic Controlled Drug Licensing for premises in Northern Ireland has been devolved to the DHSSPNI.

The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in England, Scotland and Wales. Its role is to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmacy services

in England, Scotland and Wales by upholding standards and public trust in pharmacy. Responsibility for pharmacy regulation in Northern Ireland rests with the Pharmaceutical Society of Northern Ireland.

Although the number of registered pharmacies holding Home Office licenses is small, the GPhC and the Home Office share a broader concern that controlled drugs and precursor chemicals are safely managed with pharmacy settings, by competent persons, and that the potential for diversion of is both quantifiable and minimised.

## Principles of co-operation

The DLCU and the GPhC intend that their working relationship will be characterised by:

- Making decisions that promote the safer management of controlled drugs
- Cooperating openly and transparently with the other organisation
- Respecting each other's independent status, approaches to risk, and respective systems for licensing and regulation
- Using resources effectively and efficiently to deliver best value.

## Key contacts

Details of key contacts within the DLCU and the GPhC are contained in appendix A.

## Intelligence

If either organisation receives intelligence (for example through professional whistleblowing or concerns raised by a member of the public) which:

- Indicates a significant risk in relation to the safer management of controlled drugs
- Is directly relevant to the delivery of the other organisation's functions
- Requires a coordinated multi-agency response

This information will be shared in confidence with the named contact in the other organisation at the earliest possible opportunity.

## Information

The GPhC is committed to the principle of "collect once, use many times", as a means to reducing the burden of regulation.

The GPhC routinely publishes information about the sanctions it has imposed when pharmacists and pharmacy technicians are not fit to practise, and intends to publish its assessment of registered pharmacies' compliance with its standards.

The GPhC agrees to share more detailed information supporting its assessments where this is requested. Requests for information should be sent to the named contact.

DLCU agrees to:

- Routinely inform GPhC of applications for controlled drug licences from retail (community) pharmacies, at the time of their triage, to identify any compliance issues or intelligence associated with that business, or elements of good practice

- Liaise with GPhC before any compliance visit takes place
- Share any intelligence or information with GPhC in respect of the pharmacies' compliance or licensing history, on a 'not for further disclosure' basis
- Notify GPhC of any sanctions or penalties issued to retail (community) pharmacies.

## Inspection

The GPhC alerts registered pharmacies to the possibility of inspection 4 to 6 weeks in advance, although it does not confirm the exact date and time of the inspection. Inspections are planned and undertaken by GPhC inspectors, who work in defined geographical areas.

Where registered pharmacies are known to hold Home Office licenses, the GPhC will share information about planned inspections with the DLCU, in confidence. The aims of sharing this information will be:

- To create an opportunity to alert inspectors to any relevant intelligence or information
- To avoid potential duplication of effort
- To facilitate a coordinated inspection visit if this is deemed necessary.

## Investigation

Where either organisation intends to undertake an investigation (over and above any routine inspection activity) a named contact in the other organisation should be alerted, in confidence, at the earliest possible opportunity.

Outcomes arising from any relevant investigations will be shared with a named contact at the earliest possible opportunity.

Where joint or parallel investigations are required, preliminary discussions should resolve any potential areas of conflict or overlap, arising from the organisations' respective powers.

## Enforcement

Where the GPhC has taken or intends to take enforcement action, and the outcome of this is relevant to the Home Office, details will be shared at the earliest possible opportunity.

Where the Home Office has or intends to impose sanctions or take administrative action short of prosecution, and the outcome of this is relevant to the GPhC, details will be shared at the earliest possible opportunity.

## Liaison and dispute resolution

The effectiveness of the working relationship between the DLCU and the GPhC will be ensured through regular contact, both formally and informally, at all levels up to and including the Chief Executive of the GPhC and the Home Office Head of Drug Licensing.

Any dispute between the DLCU and the GPhC will normally be resolved at an operational level. If this is not possible, it may be escalated to appropriate senior staff who will try to resolve the issues within 14 days of the matter being referred to them.

Unresolved disputes may be referred upwards through those responsible for operating this MoU, up to and including the senior executives of each organisation, who will be jointly responsible for ensuring a mutually satisfactory resolution.

### Duration and review

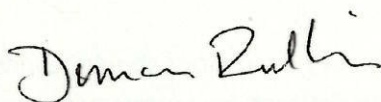
This MoU takes effect from the date of signing and will remain in force until it is terminated or superseded by a revised document.

This MoU will be reviewed no less frequently than on each anniversary of signing. Each annual review will:

- Report on actions arising from the operation of this MoU in the preceding 12 months
- Review the effectiveness of this MoU in achieving its aims, and make amendments where necessary
- Refresh operational protocols where necessary
- Identify areas for future development of the working arrangements
- Ensure the contact information for each organisation is accurate and up to date.

Signed for and on behalf of

**General Pharmaceutical Council**



Signed


Name Duncan Rudkin

Title Chief Executive and Registrar

Date 28/08/2014

Signed for and on behalf of

**Home Office**



Signed

Name Claire Gipson

Title Head of the Drugs and Firearms  
Licensing Unit

Date 15/09/2014

## Appendix A

### General Pharmaceutical Council

**Primary contact:** Hugh Simpson, Director of Policy and Communications

General Pharmaceutical Council, 129 Lambeth Road, London SE1 7BT

020 3365 3516 | [hugh.simpson@pharmacyregulation.org](mailto:hugh.simpson@pharmacyregulation.org)

**Pharmacy inspections:** Mark Voce, Head of Inspections

General Pharmaceutical Council, 129 Lambeth Road, London SE1 7BT

020 3365 3597 | [mark.voce@pharmacyregulation.org](mailto:mark.voce@pharmacyregulation.org)

- Can also provide contact details for GPhC inspectors on request

### Home Office

**Primary contact:** Angharad Thomas Steff, Head of Drugs Licensing & Compliance Unit

Home Office, 4th Floor (NW)- Fry Building, 2 Marsham Street, London SW1P 4DF

020 7035 3731 | [angharad.steff@homeoffice.gsi.gov.uk](mailto:angharad.steff@homeoffice.gsi.gov.uk)

