

Memorandum of Understanding between the Medicines and Healthcare Products Regulatory Agency and the General Pharmaceutical Council

Introduction

The memorandum of understanding (MoU) outlines the basis of cooperation between the Medicines and Healthcare products Regulatory Agency (MHRA) 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:

- 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 MHRA 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 MHRA 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 under the Data Protection Act 1998 and the Freedom of Information Act 2000.

Roles and responsibilities

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. Its aim is to protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research.

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.

Principles of co-operation

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

- Making decisions that promote patient and public safety
- Addressing overlaps and gaps in the regulatory framework
- Cooperating openly and transparently with the other organisation
- Respecting each other's independent status
- Using resources effectively and efficiently.

Key contacts

Details of key contacts within the MHRA 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 to the health and wellbeing of the public, particularly in relation to the safety of pharmacy services or the conduct of a pharmacist or pharmacy technician
- 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

Both organisations are committed to the principle of "collect once, use many times", as a means to reducing the burden of regulation.

Where it supports the effective delivery of their respective roles and responsibilities, and the aims of this MoU, both organisations agree

- To develop mechanisms to systematically and routinely share the types and categories of data (metadata) that they collect and hold
- To work towards systematically and routinely sharing identifiable data within those categories, to the extent possible by law.

The GPhC routinely publishes information about the sanctions it has imposed when pharmacists and pharmacy technicians are found to be 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.

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.

GPhC inspectors will share information about planned and performed inspections along with any relevant interim intelligence they gather with a named contact, in confidence.

The MHRA alerts wholesale dealers, including those that are also registered pharmacies, to the possibility of inspection typically up to 2 months in advance. The MHRA usually confirms the exact date and time of the inspection. Inspections are planned and undertaken by MHRA inspectors.

The MHRA Inspectorate will share information about planned and performed inspections, to the extent possible by law, along with any relevant interim intelligence it gathers with a named contact, in confidence.

The aims of sharing information about inspections between the MHRA and the GPhC 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 either organisation has taken or intends to take enforcement action, the outcome of which is relevant to the other organisation, details will be shared at the earliest possible opportunity.

Liaison and dispute resolution

The effectiveness of the working relationship between the MHRA and the GPhC will be ensured through regular contact, both formally and informally, at all levels up to and including chief executives of the respective organisations.

Any dispute between the MHRA and the GPhC will normally be resolved at an operational level. If this is not possible, it may be referred to directors of the respective organisations 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 chief executives of each organisation, who will be jointly responsible for ensuring a mutually satisfactory resolution.

Duration and review

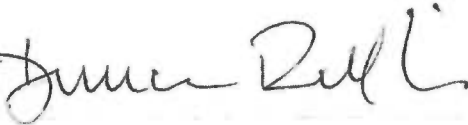
This MoU takes effect from the date of signing and will remain in force until it is terminated or superseded by a revised document.

This MoU will be formally 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 31 MARCH 2014

Signed for and on behalf of

Medicines and Healthcare Products Regulatory Agency

Signed 

Name Dr Ian Hudson

Title Chief Executive

Date

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

Pharmacy inspections: Mark Voce, Head of Inspections
General Pharmaceutical Council, 129 Lambeth Road, London SE1 7BT
020 3365 3597 | mark.voce@pharmacyregulation.org

- Can also provide contact details for GPhC inspectors on request

Medicines and Healthcare Products Regulatory Agency

Primary contact: Julie Bishop, Policy Division
MHRA, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ
020 3080 6209 | julie.bishop@mhra.gsi.gov.uk

Inspections: Mark Birse, Group Manager, Inspections
MHRA, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ
020 3080 6036 | mark.birse@mhra.gsi.gov.uk