

Memorandum of Understanding between MHRA 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).

The aims of this MoU are to:

- maintain patient and public 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

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

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

Both organisations agree to abide by the Information Commissioner's 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

MHRA is responsible for regulating all medicines and medical devices in the UK. 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

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 MHRA and the GPhC are contained in appendix A.

Information and intelligence

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

- indicates a significant concern or potential 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 relevant to the delivery of the other organisation's functions
- could require 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.

Both organisations are committed to the principle of using information more effectively, 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 will explore systematically and routinely sharing specific data sets, 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' performance against the 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.



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

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

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 GPhC contact, in confidence.

The aims of sharing information about inspections between 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 (of particular relevance to the other organisation) 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 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 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. Appendix A, which contains contact details for both organisations, will be updated as needed.

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

6th April 2016

Signed for and on behalf of

MHRA

Signed



Name

Dr Ian Hudson

Title

Chief Executive

Date

8th April 2016



Appendix A: Contact details

General Pharmaceutical Council

25 Canada Square, London, E14 5LQ

MoU primary contact: Sarah Jennings, Policy Manager Regulatory Development
0203 713 7990 | sarah.jennings@pharmacyregulation.org

Hugh Simpson, Director of Policy and Communications
0203 713 7803 | hugh.simpson@pharmacyregulation.org

Pharmacy inspections: Mark Voce, Head of Inspections
0203 713 7838 | mark.voce@pharmacyregulation.org

Regional Manager North: James Duggan
020 3713 7904 | james.duggan@pharmacyregulation.org

Regional Manager South: Tim Snewin
020 3713 7902 | timothy.snewin@pharmacyregulation.org

Regional Manager East: Colette Cooknell
020 3713 7901 | colette.cooknell@pharmacyregulation.org

Regional Manager West: Steve Gascoigne
020 3713 7903 | steven.gascoigne@pharmacyregulation.org

Professionals regulation: Chris Alder, Head of Professionals Regulation
0203 713 7837 | christopher.alder@pharmacyregulation.org

Email correspondence can also be sent to: concerns@pharmacyregulation.org

MHRA

MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ, UK

MoU primary contact: Ian Jackson, Unit Manager Inspectorate Risk, Control & Governance, IE&S
+44 (0)7768 547982 | ian.jackson@mhra.gsi.gov.uk

Inspections (General): Mark Birse, Group Manager, IE&S
+44 (0)7780 824633 | mark.birse@mhra.gsi.gov.uk

Inspections (Information/Intelligence sharing): Peter Coombs, GDP Operations Manager, IE&S
+44 (0) 7786 336349 | peter.coombs@mhra.gsi.gov.uk

Or: Tony Orme, Senior GDP Inspector, IE&S
+44 (0) 7786 336343 | tony.orme@mhra.gsi.gov.uk

All intelligence/information should be sent (or copied) to: gdp.inspectorate@mhra.gsi.gov.uk

