



Memorandum of Understanding between Healthcare Inspectorate Wales and the General Pharmaceutical Council

1. Introduction

- 1.1 The purpose of this memorandum of understanding (MoU) is to set out a framework to support the working relationship between Healthcare Inspectorate Wales (HIW) and the General Pharmaceutical Council (GPhC).
- 1.2 The working relationship between HIW and GPhC is part of the maintenance of a regulatory system for healthcare in Wales which promotes patient safety and high quality healthcare.
- 1.3 HIW is the independent inspectorate and regulator of all healthcare in Wales. The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in England, Scotland and Wales. The responsibilities and functions of HIW and GPhC are set out in Annex A.
- 1.4 This MoU is a statement of principle; more detailed operational protocols and guidance may be developed, if these are required.
- 1.5 Although HIW 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 HIW and the GPhC or their governing bodies.
- 1.6 Both organisations agree to abide by the Information Commissioners Office Data sharing code of practice1, and recognise their respective responsibilities as public bodies under the Data Protection Act 1998 and the Freedom of Information Act 2000.
- 1.7 The aims of this MoU are to:
 - maintain patient safety and confidence in pharmacy services
 - support the sharing of intelligence and information

http://www.ico.org.uk/for_organisations/data_protection/topic_guides/data_sharing

- contribute to improving the regulatory oversight of pharmacy activities
- define the circumstances in which the two organisations will collaborate.

2. Principles of co-operation

- 2.1 HIW 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.
- 2.2 Although the operational interface between the two organisations is limited, both organisations share a concern for the quality and safety of health and care services. They equally recognise the development of models of health and care service delivery which requires closer cooperation between the two organisations, and the need to create common approaches to systems regulation.

3. Key contacts

3.1 Details of key contacts within HIW and the GPhC are contained in Annex B.

4. Intelligence

- 4.1 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 relevant named contact in the other organisation at the earliest possible opportunity.

5. Information

- 5.1 Both organisations are committed to the principle of "collect once, use many times", as a means to reducing the burden of regulation.
- 5.2 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.
- 5.3 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 pharmacy businesses' 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 relevant named contact at GPhC.
- 5.4 HIW routinely publishes reports of its findings arising from inspection visits. HIW agrees to share more detailed information supporting those findings where this is requested from GPhC. Requests for information should be sent to the relevant named contact at HIW.

6. Areas for collaboration

- 6.1 HIW and the GPhC agree to collaborate strategically in developing and delivering effective regulation of their respective sectors, and recognise the interdependence between them with particular reference to:
 - the safer management of controlled drugs
 - the safety and quality of primary care services
 - new models of health and care service delivery, such as online health sites, which combine prescribing and medicine dispensing services.
- 6.2 HIW and the GPhC agree to meet regularly, as required, to
 - discuss these and other areas of concern
 - share policy and positions in the early stages of development
 - share learning, for example on the identification and management of risk and
 - review the effectiveness of working relationships between the organisations.

7. Liaison and dispute resolution

- 7.1 The effectiveness of the working relationship between HIW 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.
- 7.2 Any dispute between HIW 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.

7.3 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.

8. Duration and review

- 8.1 This MoU takes effect from the date of signing and will remain in force until it is terminated or superseded by a revised document.
- 8.2 This MoU is not time limited and will continue to take effect unless the principles described need to be altered or cease to be relevant. The MoU can be reviewed, at any time, at the request of either organisation
- 8.3 Both organisations have named a responsible person for the management of this MoU. They will liaise on a regular basis and as required to:
 - refresh operational protocols where necessary
 - identify emerging issues and areas for future development of the working arrangements
 - resolve any questions about the working relationship between the two organisations
 - annually review the effectiveness of this MoU in achieving its aims, including any actions, and make amendments where necessary
 - ensure the contact information for each organisation is accurate and up to date.
- 8.4 Both HIW and the GPhC are committed to exploring ways to develop increasingly more effective and efficient partnership working to promote quality and safety within their respective regulatory remits.

Duncan Rudkin

Chief Executive and Registrar

Jomes Zulh

Signed for and on behalf of the General Pharmaceutical Council

Date: 05 March 2015

Kate Chamberlain Chief Executive

Signed for and on behalf of Healthcare Inspectorate Wales

Date: 05 March 2015

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Responsibilities and functions

Healthcare Inspectorate Wales (HIW) and the General Pharmaceutical Council (GPhC) acknowledge the responsibilities and functions of each other and will take account of these when working together.

Responsibilities and functions of HIW

- 1. HIW is the independent inspectorate and regulator of all healthcare in Wales.
- 2. HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational autonomy. HIW's main functions and responsibilities are drawn from the following legislation:
 - Health and Social Care (Community Health and Standards) Act 2003;
 - Care Standards Act 2000 and associated regulations;
 - Mental Health Act 1983 and the Mental Health Act 2007:
 - Statutory Supervision of Midwives as set out in Articles 42 and 43 of the Nursing and Midwifery Order 2001; and
 - Ionising Radiation (Medical Exposure) Regulations 2000 and Amendment Regulations 2006.
- 3. HIW's primary focus is on:
 - making a significant contribution to improving the safety and quality of healthcare services in Wales
 - improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
 - strengthening the voice of patients and the public in the way health services are reviewed
 - ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.
- 4. HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public and others that services are safe and of good quality. Health services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services, to ensure that rapid improvement and learning takes place. In addition, HIW is the Local Supervising Authority for the statutory supervision of midwives in Wales.

Responsibilities and functions of GPhC

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

The functions of the GPhC are set out in the Pharmacy Order 2010:

- to establish and maintain a register of pharmacists, pharmacy technicians and premises at which a retail pharmacy business is, or is to be, carried on
- to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies
- to set requirements by reference to which registrants will demonstrate that their fitness to practise is not impaired
- to promote the safe and effective practice of pharmacy by registrants
- to set standards and requirements in respect of education, training, acquisition of experience and continuing professional development that is necessary for pharmacists and pharmacy technicians to achieve in order to be entered in the Register or to receive an annotation in the Register and to maintain competence
- to ensure the continued fitness to practise of registrants.

In addition, the GPhC has enforcement powers and duties under the Poisons Act 1972, the Medicines Act 1968 and the Veterinary Medicines Regulations 2013. These enforcement duties/powers mainly relate to the sale and supply of medicines from registered pharmacy premises.

The GPhC maintains an inspectorate. The GPhC Inspectors inspect all registered pharmacies in Great Britain (GB) for the purpose of ensuring its standards are met and compliance with the relevant legislation that the GPhC enforces.

Contact details

Healthcare Inspectorate Wales

Government Buildings Rhydycar Business Park Merthyr Tydfil CF48 1UZ **General Pharmaceutical Council**

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Named contacts are as follows:

HIW GPhC

MoU management

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Sarah Jennings, Policy Manager (Regulatory Development) sarah.jennings@pharmacyregulation.org 020 713 7990

Other contacts

Alun Jones, Director of Inspection, Regulation and Investigation, HIW Alun.Jones39@wales.gsi.gov.uk 0300 062 8120 Mark Voce, Head of Inspections mark.voce@pharmacyregulation.org 020 3365 3597

Hugh Simpson, Director of Policy and Communications hugh.simpson@pharmacyregulation.org 020 3365 3516

Chief Executives (Internal escalating policies should be followed before referral to Chief Executives.)

Kate Chamberlain, Chief Executive kathryn.chamberlain@wales.gsi.gov.uk

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