



# Memorandum of Understanding between Health Education and Improvement Wales (HEIW) and the General Pharmaceutical Council (GPhC)

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Date: 01/09/2020

## 1. Introduction

- 1.1. The memorandum of understanding (MoU) outlines the basis of cooperation between HEIW and the GPhC. It is intended to provide a framework to assist the joint working of the two organisations in order to support each organisation's role and functions and the aims and objective of this MoU.
- 1.2. This MoU is a statement of principle; more detailed operational protocols and guidance will be developed, as and when these are required.
- 1.3. Although HEIW 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 HEIW and the GPhC

## 2. Aims and objectives

- 2.1. The overarching aims of this MoU are to:
  - a. maintain the safe practice of pharmacy and confidence in pharmacy services and pharmacy professionals
  - b. contribute to an anticipatory and proportionate approach to regulation
- 2.2. Its specific objectives are to:
  - a. support the effective sharing of expertise and experience
  - b. support the sharing of information and intelligence as necessary to support each organisation's functions and the aims of this MoU
  - c. ensure that effective channels of communication and information sharing are established and maintained
  - d. define the circumstances in which the two organisations will act jointly and independently
  - e. facilitate working together more effectively
  - f. be transparent about areas of co-operation

## 3. Functions of the GPhC and HEIW

### GPhC

- 3.1. The 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. The functions of the GPhC are set out in the Pharmacy Order 2010 and include:
  - a. **setting standards for the education and training** of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
  - b. **maintaining a register** of pharmacists, pharmacy technicians and pharmacies
  - c. **setting the standards that pharmacy professionals have to meet** throughout their careers

- d. **investigating concerns that pharmacy professionals are not meeting our standards**, and taking action to restrict their ability to practise when this is necessary to protect patients and the public or to uphold public confidence in pharmacy
  - e. **setting standards for registered pharmacies** which require them to provide a safe and effective service to patients
  - f. **inspecting registered pharmacies** to check if they are meeting our standards.
- 3.2. In addition, the GPhC has enforcement powers and duties under the Poisons Act 1972, the Medicines Act 1968, the Humans Medicines Regulations 2012 and the Veterinary Medicines Regulations. These enforcement duties/powers mainly relate to the sale and supply of medicines from registered pharmacies.

## HEIW

- 3.3. Health Education and Improvement Wales (HEIW) is a Special Health Authority (SHA) that was established on 05 October 2017 and became operational on the 01 October 2018, following a six month period in shadow form under The Health Education and Improvement Wales (Establishment and Constitution) Order 2017 (SI No. 913 (W. 224)) “the Establishment Order”. The organisation has a wide range of functions as listed below:
- a. **Education Commissioning and Delivery** including for the whole pharmacy team
  - b. **Quality Management** to meet the required standards and make improvements where required
  - c. **Supporting regulation** HEIW liaises with regulators within the policy framework established by the Welsh Government
  - d. **Workforce intelligence** HEIW is a primary source of information about the Welsh Health Workforce and provides analytical insight and intelligence to support the development of the future workforce
  - e. **Workforce strategy and planning** HEIW provides strategic leadership for workforce planning working with Welsh Health Boards/Trusts and the Welsh Government.
  - f. **Leadership development and succession planning** HEIW is leading and planning the strategic direction for leadership and succession planning in the NHS Wales
  - g. **Careers and widening access** with a focus on opening access to people with skills currently underrepresented in our workforce
  - h. **Workforce improvement** HEIW provides strategic and practical support for workforce transformation and improvement
  - i. **Professional support for Workforce and Organisational Development**

## 4. Principles of co-operation

- 4.1. HEIW and the GPhC intend that their working relationship will be characterised by:
- a. making decisions that promote patient and public safety
  - b. sharing information and intelligence responsibly
  - c. subject to reasonable confidentiality restrictions, advising each other of matters of concern

- d. working together openly, transparently and constructively
- e. respecting each other's independent status
- f. using resources effectively and efficiently
- g. addressing overlaps or gaps in activity or information gathering

## 5. Areas of co-operation

- 5.1. HEIW and the GPhC will collaborate and exchange information necessary to fulfil their statutory functions, to protect patients and improve the quality of pharmacy services.
- 5.2. The working relationship between HEIW and the GPhC will be characterised by regular contact and open exchange of information gathered in the course of their normal business, through both formal and informal meetings at all levels. This will be kept under review by the HEIW Executive Medical Director, Pharmacy Dean and the GPhC Director for Wales who will meet on a quarterly basis.

### Concerns

- 5.3. The Pharmacy Order 2010 sets out the GPhC's duty to protect the public who use pharmacy services and the services provided by pharmacy professionals. To facilitate this work, it is important that intelligence held by HEIW that could indicate that a pharmacy professional's fitness to practise is impaired or that a pharmacy's service(s) pose a risk to the people using them, is shared with the GPhC on a timely basis.
- 5.4. HEIW is a corporate body and its functions must be carried out in accordance with its statutory powers and duties. HEIW's functions, set out in the Establishment Order and in Directions issued by Welsh Ministers (see section 3.3 of this document). The GPhC will share intelligence that impacts professional or premises registration and training programmes.
- 5.5. In general terms and subject to case law, confidential or personal information will only be disclosed if there is an overriding necessity: for example, a legal obligation or a patient or public safety reason. Personal data will be disclosed only to the appropriate staff member of the other party responsible for dealing with the issue to which such personal data relates.
- 5.6. Where HEIW or the GPhC encounter specific concerns that may impact on the work of the other, they will at the earliest opportunity convey the concerns and supporting information to a named individual with relevant responsibility at the other organisation (Appendix A).
- 5.7. HEIW will inform the GPhC of any information gathered in the course of its normal business that raises concern about ;
  - a. GPhC registrant's fitness to practise;
  - b. the safe and effective running of a registered pharmacy; or
  - c. the health, character or competence of a pre-registration trainee pharmacist
- 5.8. The information could relate but is not limited to complaints; death or injury to patients; alleged or suspected professional misconduct or health issue affecting an individual's capability; serious service failures; failure to supervise trainees; or adverse incidents or events.

- 5.9. The GPhC will, in accordance with its referral policies, inform HEIW if it is investigating concerns about the following where there may be implications for an individual's pre-registration training:
- a. the fitness to practise of a registrant who is a pre-registration tutor
  - b. the safe and effective running of a registered pharmacy that is an approved training site, or
  - c. the health, character, or competence of a pre-registration trainee pharmacist
- 5.10. If a staff member from either organisation is in doubt as to whether information should be referred, they will seek guidance from the relevant persons specified in appendix A.

### **Pre-registration training**

- 5.11. HEIW will ensure its national pre-registration (pre-foundation) training programme meets the GPhC Standards and procedures for the initial education and training for pharmacists.
- 5.12. The GPhC will approve and recognise the HEIW national pre-registration programme for all pre-registration trainees based in Wales.
- 5.13. HEIW will assess training sites in Wales for GPhC approval as pre-registration training sites.
- 5.14. The GPhC will approve pre-registration training sites in Wales based on the HEIW assessment.
- 5.15. HEIW will ensure that pre-registration tutors/educational supervisors in Wales meet published GPhC requirements.
- 5.16. HEIW will provide the GPhC with current data on pre-registration trainees, training sites and tutors/educational supervisors in Wales in accordance with jointly agreed operational protocols at defined census dates each year.
- 5.17. HEIW will carry out the functions specified for all pre-registration trainees and training sites in Wales.
- 5.18. To avoid duplication of activity, the HEIW quality management of pre-registration training in Wales will mitigate the need for GPhC quality management processes.
- 5.19. The GPhC will seek evidence and assurance annually about how the HEIW quality management of pre-registration training programmes, training sites and tutors/educational supervisors in Wales meets GPhC standards and procedures for the initial education and training of pharmacists.
- 5.20. Working together, HEIW and the GPhC will liaise with other relevant organisations that may regulate or scrutinise pre-registration training sites, such as Healthcare Inspectorate Wales, where there are matters of concern relevant to those organisation's responsibilities.

### **Enforcement**

- 5.21. 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 with the other at the earliest possible opportunity to ensure patient and public safety. Disclosure of information between HEIW and the GPhC will be considered on a case by case basis. In each case, the party holding the information will decide whether or not to disclose, after careful consideration of relevant legislation and duty of confidentiality.

### **Other**

- 5.22. Other areas of cooperation will include:

- a. Sharing of expertise and experience for example in working groups, drafting reports and guidance, conferences and in public discussion on matters of mutual relevance in order to ensure factual accuracy and to promote consistency of advice. Also, in relation to pre-registration training, such as improving operational procedures.
- b. Discussions about strategy and policy, which may impact on each other's work. Exchange of information and co-ordinating activity, for example, developments or changes in education and training policy and procedures, regulatory standards or fitness to practise criteria.
- c. Sharing trends in reported types of concerns relevant to mutual responsibilities-including concerns about trainees, registrants or registered pharmacies.
- d. Sharing information about potential media interest, or when the media have actively shown an interest, on an issue of relevance to both organisations. This may include collaboration on external communications and assisting each other's activity in the dissemination of information of mutual interest, sharing and working together in approaches to data and initiatives which may be of interest to the other organisation for modelling and planning for safe public health services.

## 6. Sharing information

- 6.1. Both organisations hold and use information about organisations and individuals to perform their core functions. The GPhC and HEIW will share information where it is necessary in order to perform these functions effectively and where it is in the public interest.
- 6.2. The organisations recognise that this exchange of information needs to be carried out responsibly and within the guidelines set out in this MoU.
- 6.3. It is understood by both organisations that statutory and other constraints on the exchange of information will be fully respected, including the requirements of data protection legislation (including the Data Protection Act 2018 and the General Data Protection Regulation ((EU 2016/679) as applied in the UK), the Human Rights Act 1998 and the common law duty of confidentiality.
- 6.4. Both organisations are committed to the principle of using information more effectively to reduce the burden of administration and 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. Where such data sets are identified, both organisations agree to develop a formal information sharing agreement.
- 6.5. Ad hoc requests for information should be sent to the contacts specified in Appendix A. Requests will be responded to in line with the receiving organisation's operational procedures and data protection legislation, as appropriate.
- 6.6. Where information shared under this MoU falls within the scope of a request for information under either the Freedom of Information Act 2000 (FOIA) or data protection legislation, the organisation receiving the request will consult the other party before any disclosure is made. This is so that they are aware of the potential impact of any disclosure on the work of the other party. Both organisations recognise that the final decision on disclosure will rest with the organisation that receives the request.

## 7. Data protection

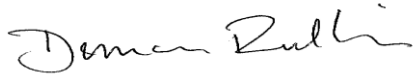
- 7.1. Both organisations recognise their respective responsibilities as data controllers under data protection legislation (including the Data Protection Act 2018 and the General Data Protection Regulation ((EU 2016/679) as applied in the UK). Both will comply with any data sharing code published by the Information Commissioner under that legislation.
- 7.2. The following principles will apply to the sharing of personal information:
  - a. There must be a fair and lawful basis for sharing information.
  - b. Information must only be used for the purpose stated at the time it is shared.
  - c. Information to be shared will be limited to what is necessary for the purpose and will be anonymised or pseudonymised where appropriate.
  - d. Shared information that is not in the public domain must be treated as confidential and must not be shared with other parties without the written agreement of the organisation that provided the information.
  - e. Information must be transmitted securely, for example by secure email or other agreed method.
  - f. Information must be stored and processed securely and in a manner that reflects its sensitivity for example, where shared information includes special category and/or criminal information.
  - g. Shared information must not be stored or shared outside the UK or European Economic Area without prior written agreement and appropriate assurances in place.
  - h. The organisation receiving personal data will apply a reasonable retention period based on the purpose for which it was shared.
  - i. Each organisation will act as an independent data controller and take appropriate steps to protect the confidential nature of documents and information that the other may provide.

## 8. Duration and review

- 8.1. This MoU is not time-limited and will continue to have effect until the principles described need to be altered or cease to be relevant. Both organisations will monitor its impact and effectiveness on an ongoing basis and it will be formally reviewed every three years. The MoU may be reviewed more urgently at any time at the request of either party and updated as required on agreement by both parties.
- 8.2. Both organisations have identified a person responsible for the management of this MoU in Appendix A. They will liaise as required to ensure this MoU is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.

Signed for and on behalf of

**General Pharmaceutical Council**



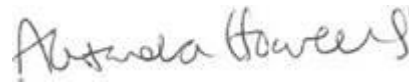
Name     Duncan Rudkin

Title     Chief Executive and Registrar

Date     23/11/2020

Signed for and on behalf of

**Health Education and Improvement Wales**



Name     Alex Howells

Title     Chief Executive

Date     29/07/2020