## General Pharmaceutical Council



# Memorandum of Understanding between the General Pharmaceutical Council and the Patient Safety Commissioner (England)

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#### 1. Introduction

- 1.1 This memorandum of understanding (MoU) outlines the basis of cooperation between the General Pharmaceutical Council (GPhC) and the Patient Safety Commissioner (PSC) for England. 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 may be developed if and when these are required.
- 1.3 Although the GPhC and the PSC 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 GPhC or the PSC.

## 2. Aims and objectives

- 2.1 The overarching aims and objectives of this MoU are as follows:
  - support the sharing of information and intelligence as necessary to support each organisation's functions and the aims of this MoU
  - ensure that effective channels of communication and information sharing are established and maintained
  - define the circumstances in which the two organisations will act jointly and independently
  - facilitate working together more effectively
  - be transparent about areas of co-operation

## 3. Functions of the GPhC and PSC

#### **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 by upholding standards and public trust in pharmacy. The functions of the GPhC are set out in the Pharmacy Order 2010 and include:
  - setting standards for the education and training of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
  - maintaining a register of pharmacists, pharmacy technicians and pharmacies
  - setting the standards that pharmacy professionals have to meet throughout their careers
  - 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
  - setting standards for registered pharmacies which require them to provide a safe and effective service to patients
  - inspecting registered pharmacies to check if they are meeting our standards.

## **PSC**

- 3.2 The Patient Safety Commissioner is an independent Ministerial appointment, funded by the Department of Health and Social Care (DHSC) and appointed by the Secretary of State. The PSC is supported by a team of DHSC Civil Servants. The PSC's line of financial responsibility is to the DHSC while the operational responsibility is to the Health and Social Care Select Committee. The core duties of the PSC are set out in the Medicines and Medical Devices Act 2021 and include:
  - promoting the safety of patients with regard to the use of medicines and medical devices
  - promoting the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.
- 3.3 The PSC's functions enable proactive interaction with providers and public bodies and so complement and enhance the existing system. The PSC has the power to make reports or recommendations to relevant public authorities and independent healthcare providers. The PSC also has the power to request and share information with these bodies which the relevant persons must cooperate with and respond to within such period as the Commissioner may reasonably require.

## 4. Principles of co-operation

- 4.1 The GPhC and PSC intend that their working relationship will be characterised by:
  - making decisions that promote patient and public safety
  - sharing information and intelligence responsibly
  - subject to reasonable confidentiality restrictions, advising each other of matters of concern
  - working together openly, transparently and constructively
  - respecting each other's independent status
  - using resources effectively and efficiently

## 5. Areas of co-operation

#### General – policy, regulatory and other thematic information

5.1 Both organisations' have a statutory role in promoting patient safety. To that end, both organisations will keep each other informed of any relevant regulatory, policy or other thematic work relating to the safety of patients, specifically with regard to the use of medicines and medical devices.

#### Investigation of individual cases and concerns

- 5.2 The GPhC has a statutory role in investigating concerns about pharmacy professionals and registered pharmacies that are not meeting relevant standards, and taking action to protect patients and the public, or to uphold public trust in pharmacy.
- 5.3 The PSC is not responsible for, and does not have the ability to investigate individual cases. The PSC can, however, consider individual cases and draw conclusions about them for the purpose of

- considering a wider, general issue. This can inform conversations they have with the sector or recommendations they may make in reports.
- The PSC may receive evidence, from a patient, member of the public or other person/organisation, which highlights a particular concern about a registered pharmacy or may suggest impaired fitness to practise on the part of a pharmacy professional. In such cases, and for the purpose of public protection where appropriate to do so, the PSC will ensure that this individual/organisation is directed to the GPhC to raise their concerns. In some cases, it may be necessary for the PSC to forward information directly to the GPhC depending on the severity of the concerns, taking account of any relevant legal or data protection considerations.

## 6. Sharing information

- 6.1 Both organisations hold and use information about organisations and individuals to perform their core functions. The GPhC and PSC 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 UK GDPR), 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.
- 6.4 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.
- 6.5 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.
- 6.6 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 (UK GDPR). 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:
  - There must be a fair and lawful basis for sharing information.
  - Information must only be used for the purpose stated at the time it is shared.
  - Information to be shared will be limited to what is necessary for the purpose and will be anonymised or pseudonymised where appropriate.
  - 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.
  - Information must be transmitted securely, for example by secure email or other agreed method.
  - 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.
  - Shared information must not be stored or shared outside the UK or European Economic Area without prior written agreement and appropriate assurances in place.
  - The organisation receiving personal data will apply a reasonable retention period based on the purpose for which it was shared
  - 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 five 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.