

Memorandum of Understanding between the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI)

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1. Introduction

- 1.1. The memorandum of understanding (MoU) outlines the basis of cooperation between the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI). 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 the GPhC and the PSNI 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 PSNI.

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 the PSNI

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 Human Medicines Regulations 2012 and the Veterinary Medicines Regulations. These enforcement duties/powers mainly relate to the sale and supply of medicines from registered pharmacies.

The PSNI

- 3.3. The PSNI the regulatory and professional body for pharmacists and registered pharmacy premises in Northern Ireland. The Pharmacy (Northern Ireland) Order 1976 is currently the principal legal basis of its operations. It protects public safety in pharmacy by:
- Setting and promoting standards for pharmacists' admission to the register and for remaining on the register; it does not currently register pharmacy technicians.
 - Maintaining a publicly accessible register of pharmacists, and pharmacy premises including the power to annotate registrants.
 - Handling and processing concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
 - The setting of minimum standards for pharmacy practices thus ensuring quality and safety for patients.
 - Ensuring high standards of education and training for pharmacists in Northern Ireland. Including lifelong learning or CPD.
- 3.4. In addition, the Pharmaceutical Society NI has enforcement powers and duties under, the Medicines Act 1968, The Misuse of Drugs Act 1971, and the Poisons (Northern Ireland) Order 1976, Regulations made under the Health Act 2006 and the Veterinary Medicines Regulations. These enforcement duties/powers mainly relate to the sale and supply of medicinal products from registered pharmacy premises.

The PSNI does not employ its own pharmacy inspectorate however, investigations and inspections are conducted by an arms-length pharmacy inspectorate in the Department of Health, Social Services and Public Safety (DHSSPS) as defined in the Pharmacy (Northern Ireland) Order 1976 and in keeping with a service level agreement with the DHSSPSNI.

Accordingly, while the PSNI sets the standards and maintains the register for pharmacy premises, approval must be first be sought from the DHSSPS inspectorate.

- 3.5. As the professional body for pharmacists it seeks to develop the pharmacy profession in Northern Ireland in the public interest. This role is conducted by a Professional Forum, an arms-length committee independent of the Council.

4. Principles of co-operation

- 4.1. The PSNI 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.

5. Areas of co-operation

General

- 5.1. The regulation of pharmacy and pharmacy professions in Northern Ireland is a devolved matter and both organisations fully acknowledge and respect the legislative role of the UK parliament and the Northern Ireland Assembly and decision-making powers of NI Ministers.
- 5.2. Both organisations' primary focus is to protect the public by promoting and maintaining standards in pharmacy. Both organisations have a shared commitment to consistency of standards for entry to, and removal from, their registers. Both organisations are committed to working together efficiently and effectively to ensure the principles of regulation remain consistent and that public confidence is maintained in Northern Ireland and Great Britain.
- 5.3. To this end, we work together to ensure that the maximum co-operation and mutual recognition is achieved within the limits of the two organisations' respective legislation. The intention is that, as far as possible, whether someone is registered with GPhC or PSNI is irrelevant in operational terms. We are building on our existing good levels of co-operation on a range of fronts, in accordance with the principles in this document.

Area 1 – Fitness to Practise and Concerns

- 5.4. 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 the PSNI 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.
- 5.5. The Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994, and subsequent amendments set out the statutory role of the PSNI. The GPhC will share intelligence regarding dual registrants or new applicants to the PSNI that may raise concerns regarding their Fitness to Practise as a pharmacist.

- 5.6. Data and insight as well as inspector-based intelligence will continue to be reviewed and where possible shared so that both organisations can have a clear understanding of the types of issues emerging within Fitness to Practise.
- 5.7. Where possible, strategies for dealing with complex or high-profile fitness to practise concerns that are likely to produce relevant learning points will be shared between both organisations so that both can continue to maintain appropriate public safety standards.

Area 2 – Education, training standards and accreditation

- 5.8. The PSNI and GPhC continue to co-operate to secure consistent standards of professional practice, in line with the principle of mutual recognition and free movement of students, trainees and pharmacists as between Northern Ireland and Great Britain. We have developed an operational protocol, to be reviewed regularly, setting out how this is to be achieved efficiently, with each organisation retaining its own accountability for formal decisions in terms of its own legal framework, and each organisation bearing its own costs and expenses and a proportionate share of any additional costs.

Area 3 – Continuing Professional Development (CPD)

- 5.9. Both the organisations require registrants to complete continuing professional development portfolios on an annual basis, albeit under different formats.
- 5.10. Previous efforts have been made as part of revalidation and continuing fitness to practise arrangements to minimise the additional regulatory burden for any individuals that hold dual registrations. Both organisations will continue to consider potential strategies how to reduce this regulatory burden, while promoting that registrants continue to update their knowledge and practice to reflect the continually shifting landscape of pharmacy practice.

Area 4 – Policy and strategy

- 5.11. Both organisations will aim to keep each other informed of relevant regulatory policy development work we are undertaking, and continue to seek ways in which consistency of standards and mutual recognition can be achieved where possible, and for the avoidance of loopholes and confusion that may be caused by differing policy approaches.

Area 5 – Registration

- 5.12. We are committed to working together to enable free movement of pharmacy professionals between Northern Ireland and Great Britain, including those qualified outside the UK. We work to maintain consistency of standards in relation to the recognition and registration of EEA and overseas pharmacists.

Area 6 – Dispute Resolution

- 5.13. In the event of any dispute about the collaborative working between the two organisations then representatives of both parties agree to meet to discuss how best to resolve the issues involved to an appropriate level. This meeting must occur within 14 days of any dispute where possible.
- 5.14. In the event of a dispute that cannot be resolved at an operational level, the issue will be referred to the Chief Executives at the GPhC and PSNI who shall endeavour to agree an appropriate resolution of the relevant dispute within 14 days of the matter being referred to them.

6. Sharing information

- 6.1. Both organisations hold and use information about organisations and individuals to perform their core functions. The GPhC and the PSNI 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 (UKGDPR). 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.