Memorandum of Understanding between
NHS LOTHIAN and the General Pharmaceutical Council

1. Introduction

1.1 This memorandum of understanding (MoU) outlines the basis of cooperation between NHS LOTHIAN and the General Pharmaceutical Council (GPhC).

1.2 The aims of this MoU are to:

- Contribute to maintaining public safety and confidence in pharmacy services
- Enable continuous quality improvement in pharmacy services
- Support the sharing of intelligence and information
- Contribute to improving the regulatory oversight of pharmacy activities
- Improve the potential for reducing the burden of inspection activities in registered pharmacies
- Facilitate effective co-operation and collaboration between NHS LOTHIAN and the GPhC.

1.3 This MoU is a statement of principle and may be supported by more detailed operational protocols and guidance if required.

1.4 Although NHS LOTHIAN 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 NHS LOTHIAN and the GPhC or their governing bodies.

2. Roles and Responsibilities

2.1 NHS LOTHIAN is one of 14 regional NHS Boards in Scotland which are responsible for the protection and the improvement of their population’s health and for the delivery of frontline healthcare services.

2.2 There are 7 Special NHS Boards and one public health body who support the regional NHS Boards by providing a range of important specialist and national services.
2.3 Each regional Board commissions and delivers services to meet the pharmaceutical care needs of patients and the public in their Board area. Each Board consists of and provides primary care, community care, acute care and public health pharmaceutical care services. Each regional Board has the responsibility to provide arrangements for the provision of pharmaceutical care services and in the community this is done in line with the Scottish Government Control of Entry arrangements and the awarding of community pharmacy contracts through each Board’s Pharmacy Practices Committee, which is a statutory committee of the Board.

2.4 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 pharmaceutical services in England, Scotland and Wales by upholding standards and public trust in pharmacy.

2.5 The functions of the GPhC are set out in the Pharmacy Order 2010 and include:
- 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.

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

2.7 The GPhC maintains an inspectorate who inspects all registered pharmacies in Great Britain to ensure GPhC standards and the legislation that the GPhC enforces are met.
3. Principles of co-operation

3.1 NHS LOTHIAN 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
- Maintaining public confidence in the two organisations
- Cooperating openly and transparently with one another
- Respecting each other’s independent status
- Using resources effectively and efficiently.

4. Key Contacts

4.1 Details of key contacts within NHS LOTHIAN and the GPhC are contained in appendix A.

5. Collaborative working

5.1 NHS LOTHIAN and the GPhC will collaborate and exchange such information as is necessary to fulfil their statutory functions and to ensure the health, safety and wellbeing of the public.

5.2 Information will be exchanged between the two organisations in accordance with a separate information sharing protocol.

5.3 It is understood by NHS LOTHIAN and the GPhC that statutory and other constraints on the exchange of information will be fully respected, including requirements under the Data Protection Act 1998, the Human Rights Act, the Freedom of Information (Scotland) Act 2002 and the UK Freedom of Information Act 2000. The principles of the common law duty of confidentiality will also be maintained.

5.4 Examples of how NHS LOTHIAN and the GPhC will collaborate and exchange information include;

a) Sharing information on strategic and policy developments which may impact on each other’s work.
b) Sharing information about trends, data approaches and initiatives which may be of interest to the other organisation.
c) Sharing learning, for example in the identification and management of risk
d) Notifying each other of risk profiling information, intelligence or specific concerns about pharmacy professionals or pharmacy services that are relevant to mutual responsibilities.
e) Collaborating on relevant external communications

6. Intelligence

6.1 If NHS LOTHIAN or the GPhC receives intelligence (for example through professional whistleblowing, concerns raised by a member of the public or during the course of an inspection or investigation) which in isolation, or in conjunction with other concerns;

- may indicate 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,
- and may be directly relevant to the delivery of the other organisation’s functions,
- or may 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.

7. Information

7.1 NHS LOTHIAN and GPhC are committed to the principle of “collect once, use numerous times” as a means of reducing the burden of regulation.

7.2 Where it supports the effective delivery of their respective roles and responsibilities, and the aims of this MOU, NHS LOTHIAN and the GPhC agree

- to develop mechanisms to share the types and categories of data (metadata) that they collect and hold systematically and routinely
- to work towards systematically and routinely sharing identifiable data within those categories

7.3 The GPhC will routinely provide NHS LOTHIAN with information about the sanctions it has imposed when pharmacists and pharmacy technicians are not fit to practise.
7.4 In the future the GPhC intends to publish its assessments of how well registered pharmacies are meeting its *Standards for Registered Pharmacies* and will routinely provide information about its published assessments to NHS LOTHIAN.

7.5 In accordance with agreed criteria, the GPhC will share additional detailed information supporting its assessment of how well a specific registered pharmacy has met its *Standards for Registered Pharmacies* where this is requested by NHS LOTHIAN. Requests for this information should be sent to the named contact detailed in Appendix A.

7.6 The GPhC will also share non-identifiable statistical information about how well registered pharmacies are meeting its *Standards for Registered Pharmacies* with NHS LOTHIAN.

7.7 NHS LOTHIAN will share relevant information about registered pharmacies and the provision of pharmaceutical services in the Board area with the GPhC. Examples of the types of information that NHS LOTHIAN will share with the GPhC include:
- additional/local services provided by registered pharmacies in the Board area based on the pharmaceutical care needs of patients (for example, dispensing of opiate substitution, supervised consumption of opiate substitution, palliative care services, injecting equipment provision, homecare service provision etc)
- new services in a Board area that are being delivered through registered pharmacies (for example, Keep Well, Weight Management etc)
- information from registered pharmacy visits by Board representatives, where these are carried out
- information from risk profiling of registered pharmacies where this is carried out.

8. Inspection

8.1 GPhC inspections are planned and undertaken by GPhC inspectors who work within defined geographical areas. The GPhC currently alerts registered pharmacies to the possibility of an inspection 4-6 weeks in advance, although it does not confirm the exact date and time of the inspection.

8.2 GPhC inspectors will share information about planned inspections with the named contact in NHS LOTHIAN in confidence. The aims of sharing this information will be
- to create the opportunity to alert inspectors to any relevant intelligence or information
- to avoid duplication of effort
• to facilitate a co-ordinated inspection and monitoring visit if this is deemed necessary

8.3 The GPhC will keep NHS LOTHIAN advised of any changes to its inspection approach or cycle.

9. Investigation

9.1 Subject to case-by-case considerations, where NHS LOTHIAN or the GPhC intend to undertake an investigation (over and above any routine inspection activity) which may impact on the other organisation’s work, they will alert the named contact in the other organisation, in confidence, at the earliest opportunity.

9.2 Where NHS Scotland Counter Fraud Services have been asked to investigate allegations relating to a pharmacist, pharmacy technician or registered pharmacy on behalf of NHS LOTHIAN, NHS LOTHIAN will alert the named contact in the GPhC at the earliest opportunity.

9.3 Outcomes arising from any relevant investigations that NHS LOTHIAN or the GPhC undertake will be shared with a named contact at the earliest opportunity.

9.4 Where joint or parallel investigations are required, preliminary discussions will be held between the NHS LOTHIAN and GPhC to resolve any potential areas of conflict or overlap arising from the organisations’ respective powers.

9.5 NHS LOTHIAN and the GPhC will work collaboratively with one another and will take all reasonable steps to ensure that they do not compromise the progress and/or success of each other’s investigations, giving due regard to criminal proceedings. There may however be occasions when NHS LOTHIAN or the GPhC needs to act swiftly in the public interest, or to protect patients. Should this occur, they will do so with due regard for other known investigations.

10. Enforcement

10.1 Where NHS LOTHIAN or the GPhC has taken independent enforcement action, the outcome of which is relevant to the other organisation, details will be shared at the earliest possible opportunity.
11. **Liaison and dispute resolution**

11.1 The effectiveness of the working relationship between NHS LOTHIAN 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. This will be kept under review by the NHS LOTHIAN Director of Pharmacy and the GPhC Director for Scotland.

11.2 Any dispute between NHS LOTHIAN and the GPhC will normally be resolved at an operational level. If this is not possible, it may be referred to executive directors of the respective organisations who will try to resolve the issues within 14 days of the matter being referred to them.

11.3 Unresolved disputes may be referred upwards through those responsible for operating this MoU, up to and including the chief executives of the organisations, who will be jointly responsible for ensuring a mutually satisfactory resolution.

12. **Duration and review**

12.1 This MoU takes effect from the date of signing and will remain in force until it is terminated or superseded by a revised document.

12.2 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
- Identify areas for future development of the working arrangements
- Ensure the contact information for each organisation is accurate and up to date.
Signatories to the agreement

Prof. Angela Timoney  
NHS Lothian Director of Pharmacy  
NHS Lothian  
5.3.15

Duncan Rudkin  
Chief Executive  
General Pharmaceutical Council  
16.3.2015
Key Contacts

NHS Lothian

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GPhC

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