Memorandum of Understanding (MOU)

Memorandum of Understanding between the Department of Health, Social Services and Public Safety Northern Ireland (thereafter known as 'DHSSPS'), the Pharmaceutical Society of Northern Ireland (thereafter known as 'PSNI'), the Health & Social Care Board (thereafter known as 'HSCB') and the Business Service Organisation (thereafter known as 'BSO'). These are collectively known thereafter as 'The Organisations'.

1.0 Introduction

The objective of this Memorandum of Understanding is to outline the arrangements that DHSSPS, PSNI, HSCE and BSO have agreed for collaboration and cooperation to support the investigation of complaints\(^1\) raised regarding pharmacists, pharmaceutical companies, pharmaceutical practice or pharmaceutical premises with the purpose of safeguarding the public in respect of the Pharmacy Networking Group\(^2\) (PNG).

It has been written in the interests of patient care and to ensure a consistent, equitable and robust approach to the handling of such complaints in Northern Ireland.

Those responsible for operational matters as outlined in this Memorandum are:

DHSSPS: Head of Medicines Regulatory Group  
PSNI: Registrar  
HSCB: Head of Pharmacy and Medicines Management  
BSO lead: AD Counter Fraud and Probity Services

2.0 Scope

The document recognises the mutual interests and underscores the close links and working relationships between the organisations and acknowledges the importance and strength of an integrated approach to complaint handling in Northern Ireland and seeks to augment that approach in order to ensure consistency and provide assurance of a common standard.

Specifically there is recognition of each of the respective organisations and their roles and responsibilities:

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\(^1\) Reference to complaint includes concerns and incidents.  
\(^2\) The Pharmacy Networking Group is a non-statutory group constituted by agreement and fully described in the Pharmacy Networking Group Terms of Reference (Appendix B).
(a) The position of the Northern Ireland Pharmaceutical Advice and Services Branch, DHSSPS in discharging the interests of the Department and its Minister allied to medicines regulation in Northern Ireland. It recognises the authority vested in the DHSSPS under the Medicines Act 1968, the Human Medicines Regulations 2012, the Pharmacy (Northern Ireland) Order 1976, the Poisons (Northern Ireland) Order 1976, the Misuse of Drugs Act 1971, the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The document also recognises that inspection and enforcement under this legislation as applies to the operation of registered pharmacies in Northern Ireland continues to be the responsibility of the DHSSPS. Operationally these matters are undertaken by the Medicines Regulatory Group thereafter known as 'MRG';

(b) The position of PSNI as the professional regulator for pharmaceutical chemists in Northern Ireland as defined by the Pharmacy (Northern Ireland) Order 1976. The document also recognises its role in the facilitation of complaints or concerns regarding the professional conduct or performance of registrants and its role in the setting of regulatory standards for practise by practitioners and their facilities or premises.

(c) The position of HSCB as the commissioning body for health and social care in Northern Ireland. General Medical Practitioners, General Dental Practitioners, Community Pharmacists and General Optometrists/Opticians collectively come under the heading of Family Practitioner Services. They are independent Contractors who have contracts for services (not contracts of employment) with the HSCB. The Health and Social Services Boards were established under the Health and Personal Social Services (Northern Ireland) Order 1972. As a result of the Health and Social Care (Reform) Act (Northern Ireland) 2009, responsibility for the contracts passed from the legacy HSS Boards to the new HSCB with effect from 1 April 2009. The Pharmaceutical Regulations (NI) 1997 govern the entry to the Board's pharmaceutical list and the terms of service for pharmaceutical contractors. The Board has the legal responsibility to ensure compliance with the terms of service in the provision of pharmaceutical services.

The document recognises its role in contractors' performance and conduct governed within a framework which includes statutory regulations, terms of service, contract documentation and professional codes of conduct.
(d) The position of BSO which acts on behalf of the HSCB with respect to payments for services, assurance for payments and investigation of potential fraud. Responsibility for exercising its function passed from the Central Services Agency (CSA) through the enactment of the Health and Social Care (Reform) Act (Northern Ireland) 2009. The BSO processes all payments for dispensing and makes payment according to the Pharmaceutical Regulations (NI) 1997 and specifically the Drug Tariff. The BSO exercises its responsibility for ensuring correct payment through Drug and Appliance Testing, probity and counter fraud activities.

The document recognises the functions of payment and assurance and the professional oversight function and how these contribute to performance and quality management.

3.0 Current Inspection and Investigation Arrangements

3.1 The Northern Ireland Medicines Regulatory Group (MRG) forms part of the DHSSPS Pharmaceutical Advice and Services Branch and is managerially accountable to the Chief Pharmaceutical Officer for Northern Ireland. It discharges those functions for which DHSSPS (and the Minister) are statutorily responsible, including for the purposes of this document, those under the Medicines Act 1968, the Human Medicines Regulations 2012, the Pharmacy (Northern Ireland) Order 1976, the Misuse of Drugs Act 1971, the Poisons (Northern Ireland) Order 1976 and Regulations made under the Health Act 2006.

3.2 It undertakes inspections of registered pharmacies (pre and post registration) against statutory provisions and the standards articulated in the Code of Conduct issued by PSNI as articulated in a separate MoU between the DHSSPS and PSNI. The MRG conducts follow up inspections and/or investigations as a result of issues highlighted or reported, or as a result of complaints raised.

3.3 The PSNI, HSCB and BSO do not undertake routine inspections or investigations in respect of the legislation detailed in 3.1. The BSO undertakes Drug and Appliance Testing in support of the Pharmaceutical Committee, constituted under the Pharmaceutical Services Regulations (Northern Ireland) 1997.
4.0 Complaint Handling Arrangements

4.1 What is a complaint?

A “complaint” is defined in “Complaints in Health and Social Care: Standards and Guidelines for Resolution and Learning” as “an expression of dissatisfaction that requires a response”. It recognises that a complainant may not always use the word “complaint”. This MoU also deals with concerns and incidents that may be highlighted by a range of individuals or bodies.

4.2 General

All organisations will have in operation complaints handling processes which have been shared with the other organisations. Every effort should be made to resolve such issues locally and in accordance with the organisation’s policy. Complaints will be treated under defined threshold criteria, where appropriate, and will be assessed by each organisation prior to involvement of other organisations e.g. those of a contractual nature may be considered under disciplinary arrangements; those that contravene statute may lead to involvement of the MRG and/or the Police; those of a solely professional nature may lead to involvement of professional regulatory bodies.

4.3 Receipt of complaint

All complaints which meet the threshold criteria, received by the organisations and which pertain to registered pharmacists or the operation of a registered pharmacy, will be referred by each organisation’s nominated point of contact to the Pharmacy Networking Group (PNG) within five working days. Discussion and agreement can be undertaken by phone, email or in person. Each participating organisation will continue to be responsible for following their internal processes for handling and managing a complaint. In sharing information with other organisations, due regard will be given to information governance as set out later. The PNG has no executive function and participation within the Group does not abrogate participant organisations from their obligations.

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4.4 Processing of complaints

On being identified as the appropriate organisation to deal with the complaint, processes will be executed in accordance with the complaints processes current within the organisation. All constituent organisations shall endeavour to process any complaint as quickly as is possible within their statutory processes.

4.5 General matters of communication and sharing of information

Each organisation is subject to regulatory requirements with regards to management of information e.g. Data Protection, Freedom of Information, Environmental Information Regulations and will therefore provide an assurance that as Data Controllers, they are compliant with statutory requirements in the storage, transfer and management of data. The working arrangements between the organisations will be characterised by regular contact and exchange of information (subject to all regulatory requirements and relevant consents). Each organisation will keep these arrangements under review, advise each other of changes as and when required and will be responsible for the information that they hold.

Each organisation will, on request provide timely advice to the other on matters within its competence, subject to the availability of resources and the absence of conflict of interests with the functions of the organisation requested to provide that advice.

Each organisation will involve the others in meetings, conferences and other public discussions relating to facilitate collaborative work where and when this is appropriate.

If a Freedom of Information request is received by any of the signatories to this agreement, requesting information that has been created by, or shared between organisations by virtue of this agreement, the organisation receiving the request will at the earliest opportunity seek the views of all other organisations prior to considering whether or not to release the information sought.

5.0 Exclusions

Only the activities specifically listed in this document are included in this memorandum of understanding.
6.0 Resolution of disagreement

Any disagreement between the organisations will normally be resolved at working level between the relevant parties. If this is not possible it will be referred to the Chief Pharmaceutical Officer, DHSSPS, The Chief Executive of PSNI, and The Chief Executives of the HSCB and BSO, who jointly will be responsible for ensuring a mutually satisfactory resolution.

7.0 Confidentiality agreement and Declaration of any conflict of interest

All PNG members will sign a confidentiality agreement (Appendix C) and a declaration of any conflict of interest (Appendix D). If circumstances change for any PNG member before the next MOU review date, this should be declared and revised form(s) completed.

8.0 Review of the Memorandum of Understanding

This Memorandum supersedes any existing memorandum and this revised version will be effective from June 2015 and will be reviewed at least every 2 years (or earlier if deemed necessary).
June 2015

Signatory Page

Signed: Dr Mark Timoney
Chief Pharmaceutical Officer
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BT4 3SQ

Signed: Mr Trevor Patterson
Chief Executive
Pharmaceutical Society of Northern Ireland
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Belfast
BT7 1HL
Tel 028 9032 6927

Signed: Ms Valerie Watts
Chief Executive
Health and Social Care Board Headquarters
12-22 Linenhall Street
Belfast
BT2 8BS

Signed: Mr D Bingham
Chief Executive
Business Services Organisation
2 Franklin Street
Belfast
BT2
Appendix A

Contact details for those responsible for operating this Memorandum:

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**PSNI**
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Registrar
Pharmaceutical Society of Northern Ireland
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BT7 1HL

**HSCB**
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BT2 8BS

**BSO**
Mr. Mark Harvey
Business Services Organisation
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Belfast
BT2 8DQ
Appendix B

Pharmacy Networking Group

Terms of Reference

Purpose

1. The purpose of the Pharmacy Networking Group (PNG) is to support the handling of pharmacy complaints\(^4\) raised through each organisation by providing a forum to communicate effectively regarding the complaint management process.

Constitution of Group

2. The group shall consist of representatives from stakeholders with an interest in pharmacy complaints and concerns – the initial group shall have representatives from the Department of Health, Social Services and Public Safety (DHSSPS), the Pharmaceutical Society of Northern Ireland (PSNI), the Health and Social Care Board (Board) and the Business Services Organisation (BSO). The group may invite other parties to join the group or attend meetings, where appropriate (this may include Trusts, RQIA).

3. Group members shall be invited to all meetings. The quorum for a meeting will be a representative from HSC (either HSCB or BSO), DHSSPS and PSNI, and all meetings will be communicated to all members.

Confidentiality agreement and Conflict of Interest

4. All group members shall sign a confidentiality agreement in relation to their membership of the PNG.

5. All group members shall complete a Register of Interests.

6. All group members shall declare an interest where a potential personal or professional conflict of interest could arise. Where a potential conflict has been identified, that person shall take no further part in that complaint allocation.

\(^4\) Reference to complaint includes concerns and incidents
Function of Group

7. It shall be the duty of the group to provide a locus to share relevant information and intelligence on complaints regarding pharmacists, pharmaceutical companies, practice and premises amongst its membership.

8. It shall be the duty of the group to consider effective methods for timely and proportionate handling of complaints and to review all subsequent outcomes as appropriate.

9. The group shall set, and regularly review, threshold criteria which may be applied when deciding whether to advance a complaint to be processed by a particular organisation including bodies external to the group. This will also include designing and maintaining such pro-forma as are deemed necessary.

10. The group has no disciplinary role.

11. The group has no executive function and does not abrogate participant organisations from their obligations

12. The group will liaise directly with other relevant organisations in advising on the development of arrangements for setting the procedures for handling complaints.

13. Nothing in the functions shall affect the responsibilities of any member organisations in meeting their obligations within their own organisations under e.g. the Data Protection, Freedom of Information, Environmental Regulations etc.

Procedures of the Group

14. Group meetings, which may be held in person, teleconference or by secure electronic means, shall be held in private.

15. It is recognised that in exceptional circumstances not all members may be able to attend and outcomes will be shared with all members in a timely manner.

16. The group shall meet not less than quarterly and on request of its members.
17. Between meetings member organisations shall, in a timely manner, share relevant information with interested parties on complaints. The secretariat should be copied into such communications. Such information will be shared and stored in a secure manner and will be accessed only by authorised personnel.

18. The PSNI shall provide the secretariat for the PNG – functions of the secretariat are outlined at 19.

Functions of the Secretariat

19. The secretariat shall act as the portal and provide assurance for the secure storage, distribution and destruction of information.

20. Information received, held and distributed by the secretariat shall be handled securely, using encryption compatible to members and providing limited access to authorised persons.

21. The secretariat shall also act as administration for the PNG, supporting meetings and distributing notes, agendas and other relevant information.

22. Information held by the secretariat may, where appropriate, be considered for non-release under the Freedom of Information Act where a case is under investigation or is related to the health of a practitioner. Sensitivity of such information may diminish over time.

23. Information will normally be shared electronically and all outcomes of meetings will be shared with all members.

24. The secretariat will provide regular summaries of all current cases and will facilitate the sharing of any learning points from relevant case files.

25. The secretariat will help facilitate the case files and ensure proportionality in their processing.

26. Certain information may be anonymised where there is any risk associated in sharing information which would reveal the identity of individuals or businesses.
Appendix C
Confidentiality Agreement

All PNG members are bound by a Common Law duty of confidence to maintain Confidentiality of information and abide by the principles of the Data Protection Act 1998.

Information provided in confidence during PNG proceedings may not be used for a purpose other than that for which it was collected or be passed to anyone else without the consent of the provider of the information. If the occasion arises where it is proposed that personal information be used for any other purposes, then expert opinion should be sought before any processing takes place.

Signed:

Title:

Date:
Appendix D

Declaration of any conflicts of interest

All PNG members are required to declare interests which are relevant and material to the functioning and constitution of the group.

Interests that shall be regarded as 'relevant and material' are:

- directorships, including non-executive directorships held in private companies or Public Limited Companies (with the exception of those of dormant companies);
- ownership or part-ownership of private companies, businesses or consultancies likely or possibly seeking to do business with Health and Social Care;
- majority or controlling share holdings in organisations likely or possibly seeking to do business with Health and Social Care;
- a position of trust in a charity or voluntary organisation involved in the field of health and social care;
- any connection with a Health and Social Care organisation, voluntary organisation or other organisation contracting for Health and Social Care services; and
- any other commercial interest in the decision before the meeting.

At the time PNG Members' interests are declared, they shall be recorded in the PNG minutes. Any changes in interests shall be declared at the PNG meeting following the change occurring.

During the course of a PNG meeting, if a conflict of interest is established, the Member concerned shall, as soon as practicable after its commencement, disclose the fact. It shall be disclosed in a manner that cannot be perceived to influence subsequent discussion or decision. The member shall withdraw from the meeting and play no part in the relevant discussion or decision.

Register of Interests - The Chair of PNG shall ensure that a Register of Interests is established to record formally declarations of interests of members. In particular the Register shall include details of all directorships and other relevant and material interests, which have been declared by PNG Members.

These details shall be kept up to date by means of an annual review of the Register in which any changes to interests declared during the preceding twelve months shall be incorporated.

The general principle to be adopted is that if there is uncertainty regarding the need to disclose a particular then, in the interests of openness, disclosure shall be made.
June 2015

A questionnaire should be completed by each PNG Member. If a PNG Member has any doubt about the relevance of an interest, this should be discussed with the wider PNG group.

In respect of each PNG member, the Register of Interests details the following:

a. Name
b. Position
c. Relevant and material interests
d. Nature of interests

PNG members will notify the Corporate Business Manager, Office of the Chief Executive, in writing of any changes in 'relevant or material' interests within four weeks of the change taking place.
June 2015

FORM FOR COMPLETION
Name of PNG Member: ________________________________

Position Held: ________________________________________________

1. Please list below any Directorships (including Non-Executive Directorships) held in private companies or Public Limited Companies (plcs).
   (Exclude Directorships held in "Dormant" Companies, - i.e. those companies with no transactions).

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2. Please list below any private companies, business or consultancies which may own (or part-own) and which may seek to do business with the HPSS (i.e. any HPSS entity).

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3. Please list below any position of authority held in Charities or Voluntary Bodies in the field of Health and Social Care.

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4. Please list below any connections which you may have with Voluntary or other bodies contracting for HSC services.

The DHSSPS has no firm definition of "connection", however, it states that you should declare any relationship which could be deemed to influence your views on any matter which may be discussed by the Board.

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5. Please list below any other interests which you consider are relevant and material.

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Signed: __________________________

Dated: __________________________