Memorandum of Understanding between The Pharmaceutical Society of Northern Ireland and The Pharmaceutical Society of Ireland

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1.0 Parties

1.1 This Memorandum of Understanding is made between:

The Pharmaceutical Society of Northern Ireland (PSNI) having its head office at 73 University Street, Belfast, BT7 1HL and

The Pharmaceutical Society of Ireland (the **PSI**), having its head office at PSI House, 15-19 Fenian Street, Dublin, D02 TD72.

1.2 The Registrar/Chief Officer of the PSI and the Chief Executive Officer of the PSNI shall have responsibility for monitoring and ensuring day-to-day compliance with the agreements set out in this Memorandum of Understanding.

2.0 Scope and Purpose

- 2.1 This Memorandum of Understanding has been agreed between the PSNI and the PSI. It is intended to provide a framework to assist the joint working of the two organisations to ensure maximum effectiveness and efficiency when carrying out their statutory functions as public bodies operating in their respective jurisdictions.
- 2.2 This MoU outlines the basis of co-operation and collaboration between the two organisations. This includes practical arrangements designed to ensure that the relationship is effective and meets each organisation's aims and objectives, particularly when there are overlapping interests and responsibilities. It sets out some of the principles underpinning the interaction between the two organisations and provides quidance on the appropriate exchange of information between them.
- 2.3 In the scope and purpose of this MoU, both parties recognise that considerable uncertainty exists as to the implications for both of the current "Brexit" process under which the UK is leaving the European Union. The MoU requires to be read, and interpreted, in the light of where this process stands at any point where the parties are acting, or proposing to act, under the terms of this MoU.
- 2.4 Details of contacts within the PSNI and the PSI are contained within Appendix A to this document.

3.0 Context in which this Memorandum of Understanding is made

3.1 Pharmaceutical Society of Ireland

The PSI, as established under the Pharmacy Act, 2007 (the 2007 Act), is charged with regulating the practice and profession of pharmacy in Ireland in the public interest. The primary objective of the PSI is to protect the public by regulating the profession of pharmacy and to supervise compliance with the 2007 Act, related medicines legislation

and instruments made under these Acts. The PSI's principal functions under the 2007 Act, are as follows:

Registration: The PSI maintains the Register of Pharmacists, Druggists, Pharmaceutical Assistants and Retail Pharmacy Businesses in Ireland. The PSI also determines and applies the criteria of registration to each Applicant as laid down in the 2007 Act and the statutory rules made thereunder.

Regulation: The PSI regulates the profession of pharmacy in the Republic of Ireland having regard to the need to protect, maintain and promote the health and safety of the public. The PSI publishes a binding Codes of Conduct for pharmacists and oversees the quality of pharmacy practice.

Education: The PSI accredits pharmacy education programmes offered in the Republic of Ireland. It also acts as the registration authority for pharmacists wishing to practise in the Republic of Ireland who have obtained their qualification outside of the Republic of Ireland and the EU/EEA and acts as the competent authority for mutual recognition of qualifications in pharmacy from other EU/EEA countries. The PSI acts to promote and ensure a high standard of education and training for persons seeking to become pharmacists, including their compliance with the statutory requirements for continuing professional development.

Inspection and Enforcement: The PSI inspects pharmacies against statutory requirements and enforces pharmacy legislation and other statutory provisions in respect of the practice of pharmacy and the sale and supply of medicines in Ireland.

Fitness to Practise/Operate: The PSI conducts inquiries to determine "fitness to practise" and "fitness to operate" and processes complaints relating to pharmacy practice and operation. The PSI may also refer matters contained in reports by its authorised officers to any public body or authority exercising relevant or complementary functions.

Improvement of Pharmacy Practice in the Public Interest: The PSI promotes and supports high standards of pharmacy practice and professionalism. PSI undertakes research and development activities in this regard and publishes guidance for the profession as to new and changing areas of practice.

3.2 The Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society of Northern Ireland is the regulatory and professional body for pharmacists 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 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

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 Pharmaceutical Society NI does not employ its own pharmacy inspectorate; however, investigations and inspections are conducted by an arms-length pharmacy inspectorate in the DoHNI as defined in the Pharmacy (Northern Ireland) Order 1976 and in keeping with a service level agreement with the DOHNI

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.

4.0 Co-operation

The PSI and PSNI are both engaged in the discharge of their respective regulatory functions in the public interest, with particular focus on the protection and enhancement of public health within their respective jurisdictions. Accordingly, there are areas of common concern to both the PSI and the PSNI as public bodies, each having a safety remit. It is therefore appropriate that both bodies agree a common understanding with regard to a range of areas of mutual concern, as follow:

4.1 Collaboration and the provision of mutual assistance in the discharge of regulatory functions in relation to the first registration, re-registration and continued registration of pharmacists.

- 4.2 Collaboration and the provision of mutual assistance in the discharge of regulatory functions in relation to the first registration, re-registration and continued registration of pharmacies.
- 4.3 Given that pharmacists play a key role in relation to ensuring the safety of the public, collaboration and mutual assistance in supporting the operation of professional disciplinary processes in each jurisdiction.
- 4.4 Given that pharmacists play a key role in relation to medication safety and usage, collaboration and mutual assistance in supporting the ongoing development of pharmacy practice for the public interest in both jurisdictions.
- 4.5 While each organisation will direct its enforcement activities towards those areas for which it is the competent authority in their respective jurisdictions, it may, in particular circumstances, be appropriate for the PSI and the PSNI to jointly co-operate and collaborate in the enforcement and execution of their enforcement functions. Such occasions will be determined and agreed on a case-by-case basis by the appropriate persons in each body who will not be below the level of Head of Regulation (or equivalent).

Where the PSI and the PSNI agree to undertake a joint enforcement operation, the duties and responsibilities of all personnel involved in that operation shall be confirmed and recorded in writing before the operation commences. All matters regarding jurisdiction, cross-border matters and any co-operation with other statutory bodies or agencies from either jurisdiction will also be agreed in advance.

- 4.6 Collaboration on joint training for staff and engagement around other opportunities for staff/management development.
- 4.7 Within the context of paragraph 2.3 and as public policy responds to Brexit within each jurisdiction, establish close working relationships designed to minimise the impacts of Brexit on patients and services.

5.0 Sharing of Information

- 5.1 In principle, subject to any applicable legal restrictions in relation to confidentiality and data protection, where matters come to the attention of either body in the course of its activities that it considers to be of concern to the other, each organisation will co-operate as far as possible to ensure that the relevant information is shared in a timely manner with the other organisation.
- While every endeavour will be made to facilitate such early sharing of information, it is understood by both parties that there may be occasions on which there may be legal or other impediments which prevent sharing of either some or all of such information.
- 5.2 Information may be shared between the two bodies in relation to:
 - Registration status of pharmacists and/or retail pharmacy businesses.
 - Concerns regarding the practise of pharmacists and the operation of retail pharmacy businesses.

- Any other information that is considered appropriate or relevant by either organisation and which relates to the areas of cooperation set out in paragraph 4 of this MOU.
- It is noted that PSNI is a proactive discloser as regards international alerts and recognises that the PSI may not always be in a similar position given different legislation in its jurisdiction.
- 5.3 The sharing of confidential information shall be on the basis of criteria, to be agreed at the time, but before, the particular information is proposed to be shared by both organisations with particular regard to:
 - (i) protecting the source of that information, and
 - (ii) the best interests of public health and welfare.

Such criteria shall take into account, among other matters, the requirements of Freedom of Information legislation and data protection/data privacy requirements within both jurisdictions. Where appropriate, such information shall be anonymised before being shared.

No confidential information shall be disclosed without reference to the supplier of that information.

- 5.4 Except as required or permitted by law, information shared between PSI and the PSNI will not be provided to third parties without the written consent of the originating person or body.
- 5.5 Provision of information will be considered on a case by case basis and in the interests of public safety and wellbeing with reference to the following criteria:
 - a) Each party shall endeavour to respond to a request for information within 14 days.
 - b) In the event that a request for information is refused, the party refusing the request shall provide reasons, normally in writing.
 - c) Where information which is shared is subject to an embargo date for public dissemination, each organisation will respect the embargo date.
- 5.6 The parties will notify each other without delay if they become aware that information shared under this Memorandum of Understanding is not accurate, complete and/or up to date.

6.0 Communication and other issues

6.1 The PSI and the PSNI recognise and acknowledge the important role that education has to play in ensuring the wider knowledge and understanding of the regulatory and administrative frameworks that govern the provision of safe and quality health services to the public. To this end, both bodies are committed, where relevant, to sharing and working together on the provision of guidance and information for pharmacists, retail pharmacy businesses, other stakeholders and the wider public as appropriate.

Areas of specific interest in this regard include, but are not limited to:

- a) Ensuring that provisions relating to the receipt, storage, dispensing, compounding, preparation, supply, recording and destruction of all medicinal products (including controlled drugs) are fully understood and complied with.
- Advanced services provision in registered pharmacy premises including, but not limited to, Patient Group Directives such as Flu and travel vaccination and emergency contraception,
- Matters associated to the supplies of Veterinary medications and medicinal/nonmedicinal Poisons
- d) Promoting knowledge and understanding of all matters concerning medicines management and their safe and rational use.
- 6.2 Both bodies also endeavour to collaborate on external communications. Areas of specific interest in this regard include, but are not limited to:
 - a) Involving each other, as appropriate, in conferences and public discussions about matters of mutual concern.
 - b) Involving each other, as appropriate, in working groups, meetings and discussions on matters of mutual relevance.
 - c) Ensuring that potential and actual complainants receive accurate and helpful information on the appropriate avenue for pursuing their concerns.
- 6.3 Both the PSI and the PSNI are committed to ensuring that each body understands the roles, functions, policies and administrative procedures of the other. Accordingly, both bodies are committed to maintaining and further developing each body's knowledge and understanding of the other by whatever mutually agreeable means, as determined by both bodies, would facilitate partnership and co-operation in the discharge of each body's respective functions in the public interest within their respective jurisdictions.

7.0 Legislation

7.1 It is agreed that each body will, insofar as is possible and as appropriate, include the other in the process of consultation on proposals for new or amended legislation that is of mutual interest and concern.

8.0 Annual meeting

8.1 In light of the range of issues of mutual concern to the PSI and the PSNI, it is agreed that the senior management of both bodies will meet on an annual basis to consider and review these issues in accordance with the provisions of this Memorandum of Understanding.

9.0 Commencement and Termination

- 9.1 This Memorandum of Understanding shall take effect upon a signature of both parties and shall continue until such time as it is terminated or superseded by a revised document.
- 9.2 This Memorandum of Understanding may be terminated upon written notification by one party to the other with 28 days' notice.
- 9.3 The provisions in this Memorandum of Understanding, within the context of paragraph 2.3, will be reviewed no later than three years from the date it was signed by the parties. The provisions in this Memorandum of Understanding can also be reviewed at any time at the request of either party. Both parties are committed to resolving any issues arising under this Memorandum of Understanding by normal administrative means and in a spirit of mutual cooperation.

10.0 Legal Effect

- 10.01 Nothing in this Memorandum is intended to:
 - a) Create binding obligations or affect existing obligations under applicable international, EU or domestic law in either jurisdiction;
 - b) Create a commitment that conflicts with either party's national laws, court orders or any applicable international or EU legal instruments; or
 - c) Create expectations of cooperation that would exceed a party's jurisdiction.

Trevor Patterson

Chief Executive Officer

on behalf of the Pharmaceutical Society of Northern Ireland

Niall Byrne

Registrar and Chief Officer

on behalf of the Pharmaceutical Society of Ireland

Appendix A

List of Main Contacts

Name:	Position:	Contact No.	E-mail address:
Trevor Patterson	Chief Executive	00442890326927	Trevor.patterson@psni.org.uk
Brendan Kerr	Registrar and head of regulation	00442890326927	Brendan.kerr@psni.org.uk
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Laurence Fay	Registration [operational issues]	00442890326927	Laurence.fay@psni.org.uk

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