Memorandum of Understanding

Health Information and Quality Authority

and

The Pharmaceutical Society of Ireland (PSI) – The Pharmacy Regulator

17 12 2024

1. The Parties

The **Health Information and Quality Authority,** having its head office at Unit 1301 City Gate, Mahon, Cork, Ireland.

And

The **Pharmaceutical Society of Ireland**, having its head office at PSI House, 15-19 Fenian Street, Dublin 2, D02 TD72

2. Interpretation and Definitions

2.1 This Memorandum of Understanding means the clauses of and the appendices to this Memorandum of Understanding, all of which shall be read as one document.

2.2 In this Memorandum of Understanding, the following definitions shall apply:

(i) "2007 Act" means the Health Act 2007 as amended from time to time;
(ii) Data Protection Law means all applicable laws and regulations relating to the processing of Data, including, in particular, the GDPR, the Data Protection Acts 1988- 2018, the Data Sharing and Governance Act 2019 and any statutory instruments, rules, orders or regulations made thereunder as from time to time amended, extended, re-enacted, replaced or consolidated (whether before or, after the date of this Agreement)
(iii) "HIQA" means the Health Information and Quality Authority and shall include the Chief Inspector of Social Services where relevant;
(iv) "MOU" means this Memorandum of Understanding;
(v) "PSI" means the Pharmaceutical Society of Ireland
(vi) "parties" means HIQA and the PSI and "party" means either of them;

3. Background

3.1 The parties wish to enter into this MOU to establish a framework for cooperation and information sharing in areas of mutual responsibility and shared interest which fall within their respective remits.

3.2 The parties agree that the MOU entered into between the parties on 28 June 2016 is hereby terminated and this MOU shall come into effect in accordance with clause 9 of this MOU.

4. Legislative Mandate

Statutory Role, Functions and Powers of HIQA

4.1 HIQA, having been established under the 2007 Act is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

- **Regulating health services** — Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.

- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

4.2 Under Section 8(2)(b) of the 2007 Act, in carrying out its functions, HIQA shall have regard to the need to co-operate with and co-ordinate its activities with public authorities, the performance of whose functions affect or relate to the functions of HIQA, other than those functions described in section 8(1)(c), (d) and (l) of the 2007 Act. The functions described in section 8(1)(c), (d) and (l) are monitoring compliance with standards, undertaking investigations where there may be a serious risk to the safety, health or welfare of a person receiving services in respect of which HIQA has set standards and advising the Minister for Children, the Health Service Executive and the Child and Family Agency as to the level of compliance by the HSE and service providers with the standards set by HIQA

4.3 Under Section 38 of the 2007 Act, HIQA may, subject to any directions given by the Minister for Health under Section 29 of the 2007 Act, and on the terms and conditions HIQA sees fit to impose, give assistance to a body which performs or proposes to perform a function similar or ancillary to a function that HIQA may perform.

4.4 Section 8(3) of the 2007 Act provides that HIQA has all the powers as are necessary or expedient for the performance by it of its functions.

4.5 **Statutory Role, Functions and Powers of the PSI**

The Pharmaceutical Society of Ireland (PSI – The Pharmacy Regulator) is a public body established in law to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland.

The principal function of the PSI is to ensure patient safety and public protection. The PSI is committed to carrying out its work independently, ethically and transparently. The Pharmacy Act 2007, as amended, establishes the statutory role and responsibilities of the PSI as the pharmacy regulator, which includes;

- Registration of pharmacists, pharmaceutical assistants and pharmacies;
- Setting standards for pharmacy education and training and ensuring all registered pharmacists are undertaking appropriate continuing professional development (CPD);
- Promoting good professional practice by pharmacists, by raising standards and sharing information for the benefit of patients and the wider health system;
- Assessing compliance and taking actions to address poor performance, practices and behaviours through its inspection and enforcement functions, by considering formal complaints made against a pharmacist or a pharmacy and through the imposition of sanctions;
- Providing advice, support and guidance to the public, pharmacy profession and Government on pharmacy care, treatment and services in Ireland.

5. Purpose and Objectives

5.1 The purpose of this MOU is to provide a framework for co-operation and communication between the parties to ensure maximum effectiveness and efficiency when performing their respective statutory functions. The parties recognise that there are areas where the performance of the functions of HIQA and PSI may affect or relate to the functions of the other party to this MOU.

5.2 This MOU is intended to cover areas of common interest where cooperation will lead to improved health and social care services for the benefit of the health and welfare of service users and in the interest of service-user safety and public protection.

5.3 The objectives of this MOU are:

a) to promote cooperation and consultation, where appropriate, on mutual areas of strategic and high level operational interest in order to promote a common understanding of the statutory responsibilities, working procedures and legal powers and constraints of each of the parties;

b) to examine or pursue opportunities, and where appropriate, to collaborate on initiatives within each parties' statutory remit, where it is deemed by the parties to be in the interests of promoting the safety and quality of health and social care services for the benefit of service users;

c) to facilitate and provide the necessary safeguards for the cross referral of information of concern, where one party believes that the information falls within the statutory remit of the other or both. Both parties will respect, maintain and adhere to all requirements of relevant legislation.

6. Primary Areas of Cooperation

6.1 The parties recognise that they may communicate and cooperate, in particular, in relation to the following matters (without limitation):

(a) To consider, consult and collaborate on joint projects or initiatives, where appropriate and where it is within both parties' statutory remit.

(b) To promote consultation and share best practice learnings, where appropriate, in relation to the implementation of mandated Government policy in so far as it relates to areas of mutual interest and responsibility of each party.

(c) On cross referral of information of concern, where appropriate, where one party believes that the information of concern falls within the remit of the other; in this regard both parties will respect, maintain and adhere to all requirements of the relevant legislation;

(d) For HIQA this includes but is not limited to: circumstances where HIQA becomes aware of information of concern which may relate to potential deficits in the safety, quality and standard of pharmacies and/ or services provided by pharmacists and /or pharmaceutical assistants registered with the PSI; this may include concerns regarding the provision of a service that may lead to a risk to the safety of service user/s, a patient or the public.

(e) For the PSI this includes but is not limited to: circumstances where the PSI, through its inspection, registration, or monitoring functions or through its investigations or compliance processes becomes aware of information of concern which may relate to potential deficits in the safety, quality and standard of services regulated or monitored by HIQA; this may include concerns regarding the provision of a service that may lead to a risk to the safety of service users;

(f) To consult each other where deemed relevant in relation to any significant new strategic or policy proposals likely to affect the other party and to provide such relevant information or advice as necessary;

(g) To engage in joint training or knowledge sharing exercises involving their respective employees where doing so would support the purposes of the MOU;

(h) Any other matter in respect of which the parties agree their cooperation would be in keeping with the spirit of this MOU or desirable in the public interest.

7. Exchange of Information

7.1 The parties will ensure that any disclosure of information under the terms of this MOU is carried out in a manner that is prompt, efficient, proportionate and fully in compliance with legislation to which the parties are subject including but not limited to, Data Protection Law, the 2007 Act, the Pharmacy Act 2007,

the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and the Protected Disclosures Act 2014 and any amendments to this legislation.

7.2 The parties will, where appropriate, anonymise information or personal data before it is transferred to the other party.

7.3 Any sharing of information or personal data undertaken between the parties will be appropriately documented and will be subject to strict access and security controls and will ensure secure disposal of shared data.

7.4 The parties may enter a Data Sharing Agreement which will set out the legal basis for the sharing of any personal data pursuant to this MOU. No personal data shall be shared by the parties unless there is a lawful basis and it is necessary and proportionate to do so.

7.5 The parties agree not to use any information or personal data disclosed under this MOU for any purpose other than the purpose of performing its statutory obligations.

7.6 Without prejudice to any obligations under the Freedom of Information Act 2014, Data Protection Law or any other statutory obligations that either party may have, the parties will not disclose any information received under the terms of this MOU to any third party without first obtaining the consent of the party that provided such information.

7.7 Nothing in this MOU requires the parties to disclose personal data or confidential information except in accordance with law.

8. Liaison and Communication

8.1 The parties agree to meet once every calendar year and more regularly where necessary to review the effectiveness of this MOU and identify any issues that require to be addressed. Strategic, policy and operational meetings will be arranged as required and as agreed between designated contact persons.

8.2 All communication between the parties pursuant to this MOU will be carried out via the designated contact persons as set out in Appendix 1 of this MOU. This is in order to ensure that matters are dealt with by the appropriate person.

8.3 Upon signing of this MOU, each party will ensure that the identity and contact details (name, email and telephone number) of the designated contact person as set out in Appendix 1 of this MOU will be exchanged with the other party. In the event that

there is a change in the identity of a designated contact person during the term of this MOU, the relevant party will inform the other party of same and will forward the identity and contact details of the appropriate designated contact.

8.4 Communication will be conducted between designated contact persons on a formal basis through scheduled meetings and informally as and when required.

8.5 The parties agree, to exchange any concerns or report any incidents in writing in accordance with Clause 7 of this MOU except in the case of an emergency where information can be exchanged orally. In the case of an emergency, where information has been exchanged orally, the disclosing party agrees to record the exchange in writing and will share it with the receiving party within a reasonable timeframe.

8.6 Each party will, before publishing any materials, statements, reports or press releases on a joint partnership, project or initiative notify the other party in advance of the publication and provide sufficient detail to the other party on the proposed publication.

8.7 The parties agree to publish this MOU on their respective websites.

9. Miscellaneous Matters

Legal Status of MOU

9.1. Each party acknowledges that this MOU does not create any legally binding obligations of any nature on either party. This MOU reflects the intentions of the parties who will in good faith observe and give due respect to the agreed terms of the MOU.

Variation

9.2 Any provision of this MOU may be amended at any time by the mutual consent in writing of the parties via the respective signatories.

Effective date

9.3 This MOU will come into effect upon the date of signature of both parties and will continue in effect until its termination.

Formal Review

9.4. This MOU will be subject to a formal review every three years from the date of its signing or otherwise as requested by a party to this MOU. The content of this MOU will be reviewed to ensure that it remains relevant, fit for purpose and up to date.

Termination

9.5 Each party may at any time give written notice of termination of this MOU to the other party. This MOU will terminate three months after the date of receipt of the notice of termination. The termination of this MOU will not affect the confidentiality undertakings expressed by the parties in this MOU or any commitments given under, or as a consequence of, this MOU in respect of any arrangements or action taken during the period before the termination takes effect.

Execution

9.6 This MOU may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. The parties have the option to execute this MOU by means of a simple electronic signature or advanced electronic signature or qualified electronic signature which shall be considered as an original signature and shall have the same validity, enforceability and permissibility as the original signature for the purpose of this MOU.

No Disclosure if prohibited

9.7 This MOU does not operate to require either party to disclose information to the other party if the disclosure of that information by the party concerned is prohibited by law.

Exceptional cases

9.8 While it is intended that the arrangements in this MOU should apply generally, it is recognised that some circumstances will require special handling. Nothing in this MOU prevents the making of arrangements to meet specific exceptional circumstances.

Disputes

9.9 The designated contact persons agree to act in good faith and to make efforts to resolve any dispute arising on foot of this MOU amicably. In the event, that the designated contact persons cannot resolve the matter, it will be referred to the Chief Executive Officer or person with equivalent title of each party who will endeavour to resolve the matter.

IN WITNESS where of this ***Memorandum of Understanding*** has been entered into on the DD MM 2024.

Signed by Angela Fitzgerald

Chief Executive Officer

Health Information and Quality Authority

Date: 17.12.2024

Signed by Joanne Kissane

Registrar and Chief Officer

Pharmaceutical society of Ireland

Date: 23.10.2024

PSI
The Pharmacy Regulator
An Rialtóir Cógaisíochta

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Appendix 1 - Designated Contact Persons

Area of Liaison and Communication	HIQA	The PSI
Regulation/Monitoring	Director of Healthcare Regulation Head of Programme Healthcare(s)	Head of Community Pharmacy Assurance
Standards	Director Health Information and Standards	Head of Community Pharmacy Assurance
Data Protection	Data Protection Officer	Head of Governance and Programme Delivery
Freedom of Information	Freedom of Information Officer	Head of Governance and Programme Delivery
Dispute Resolution	Chief Executive Officer	Registrar and Chief Officer