Memorandum of Understanding between the Health Information and Quality Authority and the Pharmaceutical Society of Ireland

Approved and Signed	Date
Version 1.0	14/12/2010
Version 2.0	28/06/2016

Contents

1.0 Parties

1.1 This Memorandum of Understanding is made between:

The Health Information and Quality Authority (**HIQA**) having its head office at Unit 1301 City Gate, Mahon, Cork; and

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

1.2 The Registrar/Chief Officer of the PSI and the Chief Executive Officer of HIQA 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 HIQA 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.

2.2 It 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 guidance on the exchange of information between them.

2.3 Details of contacts within HIQA 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 is charged with regulating the practice and profession of pharmacy in Ireland in the public interest. The primary objectives of the PSI are to lead, regulate and develop the profession of pharmacy and to supervise compliance with the Pharmacy Act, 2007 and instruments made under it. The PSI's principal functions under the Pharmacy Act, 2007 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 Pharmacy Act, 2007 and the statutory rules made thereunder.

Regulation: The PSI regulates the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public. The PSI draws up codes of conduct for pharmacists and oversees the quality assurance and application of best practice across the sector.

Education: The PSI accredits undergraduate pharmacy degree programmes offered in the State and acts as the registration authority for pharmacists wishing to practise in Ireland who have obtained their qualification outside 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 continuing professional development.

Inspection and Enforcement: The PSI has the power to inspect pharmacies, enforce pharmacy legislation and enforce various statutory provisions in respect of the practice of pharmacy and the sale and supply of medicines in Ireland. Section 7(2) (b) of the Pharmacy Act, 2007 gives the Council of the PSI the power to authorise persons to exercise the powers of entry and inspection of drugs and documents, as set out in section 24 of the Misuse of Drugs Act, 1977[1] and appoint persons as authorised officers for the purposes of the Irish Medicines Board Acts, 1995 and 2006 and furnish them with warrants, for the purposes of section 32B of that Act.

Fitness to Practise/Operate: The PSI conducts inquiries to determine "fitness to practises" and "fitness to operate" and processes complaints relating to pharmacy practice and operation. Under the Pharmacy Act, 2007, the Registrar of the PSI has the power, when directed by Council, to refer matters relating to reports of investigation by authorised officers, as required, to any public body or authority exercising functions which are relevant to the matters considered by the Council.

Improvement of Pharmacy Practice in the Public Interest: The PSI promotes the highest standards of pharmacy practice. Under the Pharmacy Act, 2007, the PSI has the power to make public statements about any aspect of pharmacy to which its functions relate.

Governance: The PSI is governed by a 21 Member Council consisting of a non-pharmacist majority. By virtue of section 10(3)(a) of the Act, this includes one member of Council to be nominated by the Health Products Regulatory Authority as representative of the management of the regulation of medicinal products.

3.2 **Health Information Quality Authority**

HIQA was established on a statutory basis in May 2007, following the signing into law of the Health Act, 2007. The primary objectives of HIQA are to drive quality, safety, accountability and the best use of resources in health and social care services, whether delivered by public, voluntary or private bodies.

[1] This requires the commencement of section 9 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (*No. 3 of 2006*).

HIQA's mandate extends across the quality and safety of the public, private (within its social care function) and voluntary health and social care services. Its remit includes setting standards, monitoring compliance with standards and regulations, and carrying out investigations where there are reasonable grounds to do so.

The Office of the Chief Inspector of Social Services within HIQA registers designated centres, including nursing homes and centres providing residential services to children and adults with disabilities. HIQA may also provide advice and recommendations to the Department of Health and the HSE in respect of information identified respecting the services and health and welfare of the population.

4.0 Co-operation

The PSI and HIQA 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. Accordingly, in serving the public interest, there are a number of areas of common concern to both the PSI and HIQA. It is therefore appropriate that both bodies agree a common understanding with regard to a range of areas of mutual concern as follows:

4.1 Collaboration in the discharge of regulatory functions in relation to people residing in designated centres (residential centres or nursing homes).

The Office of the Chief Inspector of Social Services within HIQA is responsible for protecting, maintaining and promoting the health and welfare of residents in designated centres through the registration and inspection of designated centres, maintaining registers of designated centres and promoting and ensuring safe, quality and high standards of care in designated centres.

Pharmacists play a key role in the creation and delivery of high quality person focused care. In order to ensure residents in designated centres are protected it is essential that they receive services from competent pharmacists.

While each organisation will direct its enforcement activities towards those areas for which it is the competent authority, it may in particular circumstances, be appropriate for the PSI and HIQA to jointly co-operate and collaborate in the enforcement and execution of their statutory functions. Such occasions will be determined and agreed on a case-by-case basis by the appropriate persons in each body.

Where HIQA and the PSI agree to undertake a joint enforcement operation the duties and responsibilities of all personnel involved in that operation shall be confirmed and recorded before the exercise commences. Joint training for inspectors/ investigators in areas of mutual interest will take place, wherever possible.

5.0 Sharing of Information

5.1 In principle, 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. However, while every endeavour will be made to facilitate such 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 either body from informing the other.

5.2 Information may be shared between the two bodies in relation to:

- Registration status of pharmacists and/or retail pharmacy businesses providing services to designated centres.
- Registration status of designated centres which are being supplied with products and services by a registered retail pharmacy business.
- Concerns regarding the practise of pharmacists and the operation of retail pharmacy businesses providing services to designated centres.
- Concerns regarding the practise of registered providers, the person in charge and the operation of designated centres with particular reference to issues associated with medicines management within the designated centre.
- Any other information that is considered appropriate or relevant by either organisation.

5.3 The sharing of confidential information shall be on the basis of criteria agreed 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 the requirements of the Freedom of Information Act 2014 and Data Protection Acts 1988 and 2003. Where appropriate, such information shall be anonymised before being shared.

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

5.4 Except as required or permitted by law, information shared between HIQA and the PSI will not be provided to third parties.

5.5 Provision of information will be considered on a case by case basis and in the interests of public health.

1. Each party shall endeavour to respond to a request for information within 14 days.
2. In the event that a request for information is refused, the party refusing the request shall provide reasons, normally in writing.
3. Where information which is shared is subject to an embargo date for public dissemination, each organisation will respect the embargo date.

6.0 Communication and other issues

6.1 The PSI and HIQA recognise and acknowledge the important role that education has to play in ensuring the wider knowledge and understanding of the regulatory and administrative frameworks and their implementation and operation that govern the provision of safe and quality services to the public. To this end, both bodies are committed, where relevant, to sharing and working together on the provision of guidance for pharmacists, retail pharmacy business owners, registered providers, persons in charge, other stakeholders and the wider public as appropriate.

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

1. 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.
2. Ensuring that provisions relating to the regulatory framework and associated quality standards for medicines management within designated centres are fully understood and complied with, having regard for patient safety and public protection.
3. 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:

1. Involving each other, as appropriate, in conferences and public discussions about matters of mutual concern.
2. Involving each other, as appropriate, in working groups, meetings and discussions between organisations on matters of mutual relevance.
3. 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 HIQA are committed to ensuring that each body has a full and complete understanding of 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, determined by both bodies, so as to facilitate partnership and co-operation in the discharge of each body's respective functions in the public interest.

7.0 Legislation

7.1 Both the PSI and Authority, at the request of the Department of Health, routinely advise on the drafting and introduction of legislation falling within the remit of their respective statutory roles and functions. It is agreed that each body will, insofar as is

possible and 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 Meetings

8.1 In light of the range of issues of mutual concern to the PSI and HIQA, it is agreed that the senior management of both bodies will meet on an annual basis to consider and review these 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 will be reviewed after three years from the date it was signed by the parties, and any amendments made by agreement. The provisions in this Memorandum of Understanding can 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.

Signed by PHELIM QUINN
Chief Executive Officer
on behalf of the Health
Information and Quality Authority

28/6/16
Date

Signed by DAMHNAIT GAUGHAN
Acting Registrar and Chief Executive Officer
on behalf of the Pharmaceutical
Society of Ireland

28 June 2016
Date