Memorandum of Understanding between the Irish Medicines Board and the Pharmaceutical Society of Ireland

1. Parties

1.1 This Memorandum of Understanding is made between the Irish Medicines Board (IMB) and the Pharmaceutical Society of Ireland (PSI).

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

2. Scope and Purpose

2.1 This Memorandum of Understanding has been agreed between the IMB and the PSI. It applies to the Republic of Ireland only and 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 the IMB and PSI are contained within Appendix A to this document.

3. Context in which this Memorandum of Understanding is made

3.1 Pharmaceutical Society of Ireland

The Pharmaceutical Society of Ireland (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 application 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 and acts as the competent authority for mutual recognition of qualifications from other EU countries. The PSI acts to promote and ensure a high standard of education and training for persons seeking to become pharmacists, including continuing professional development.

Inspection and Enforcement: The PSI has the power to inspect pharmacy practices, 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 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 instructed 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. As specified under Part. 3 S. 10 (3) (a) one member of Council shall be nominated by the IMB as a representative of the management of the regulation of medicinal products.

3.2 Irish Medicines Board

The Irish Medicines Board (IMB), as established by the Irish Medicines Board Acts, 1995 and 2006, is the competent authority in Ireland for the regulation of medicinal products for human and veterinary use, medical devices for human use, human blood and blood components for transfusion, and tissues and cells intended for human application.

The primary objectives of the IMB are to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products. The IMB's principal functions under the Acts are as follows:

Medicinal products: The IMB assesses applications and grants marketing authorisations for medicinal products for human or veterinary use. It participates as a Member State in the assessment of applications for marketing authorisations granted by the European Commission. It approves the conduct of clinical trials on human medicines In Ireland and advises the Department of Agriculture, Fisheries and Food in relation to clinical trials on veterinary medicines. The IMB inspects and authorises manufacturers and wholesalers of human medicines and manufacturers of veterinary medicines. It operates a pharmacovigilance system for the collection and evaluation of suspected adverse reactions to medicinal products. It evaluates and acts on quality defects in marketed medicinal products, oversees recalls and manages a sampling and analysis programme.

Medical devices for human use: The IMB designates the notified bodies in Ireland which grant CE marks to medical devices and maintains a register of certain medical devices placed on the Irish market. It operates a vigilance system for the collection and evaluation of incidents attributable to medical devices, oversees recalls of defective devices from the market and carries out market surveillance relating to medical devices.

Blood and tissues & cells establishments: The IMB inspects and authorises establishments which collect, test, process, store and distribute human blood and blood components, and sites involved in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. It operates a vigilance system for the notification of suspected Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) associated with human tissues and cells.

Controlled drugs: The IMB operates a system for inspection and licensing of the import, export and storage of drugs controlled under the Misuse of Drugs Act 1977; the power to grant licences is intended to be transferred from the Department of Health and Children to the IMB.

Enforcement: The IMB enforces the legislation relating to all of the above areas, except those relating to veterinary medicinal products and controlled drugs.

Governance: The IMB is governed by a nine-member Board appointed by the Minister for Health and Children. There are three advisory committees, for human medicines, veterinary medicines and medical devices.

4. Co-operation

The PSI and the IMB 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 and animal health. In summary, the IMB is the competent authority for the authorisation, manufacture and wholesaling of medicinal products, which includes their

sale and supply and for the process of CE marking and market surveillance of medical devices in Ireland. The PSI is the competent authority for regulating the practise and operation of a Retail Pharmacy Business, which includes aspects of supply. Accordingly, in serving the public interest, there are a number of areas of common concern to both the PSI and the IMB. 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

Both the PSI and the IMB have powers of enforcement in relation to Regulations made under the IMB Acts 1995 and 2006.

While each will direct its enforcement activities towards those areas for which it is competent authority, it may in particular circumstances, be appropriate for the PSI and the IMB 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. These joint operations may also involve the participation of other related agencies such as the Department of Health & Children, the Department of Agriculture, Fisheries & Food, the Health Service Executive and An Garda Síochána.

Where the IMB 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.

4.2 Collaboration in the area of Sale & Supply of Medicinal Products and Medical Devices

The practice of pharmacy includes the sale or supply of medicinal products for human or veterinary use. As such, the arrangements for the supply of a medicinal product, the scheduling of a medicinal product for supply, the availability of products and other matters relating to the sale and supply of a medicinal product or medical device is of direct bearing to the practice of pharmacy and is consequently of interest to the PSI.

The IMB is responsible for the authorisation of human and veterinary medicinal products and monitoring of medical devices in accordance with the existing regulatory provisions. In relation to medicinal products for human use it has a specific role in assigning the sale or supply classification to each medicinal product that is the subject of a marketing authorisation.

Both the PSI and IMB acknowledge the interest and involvement of each other in matters pertaining to the sale and supply of medicinal products and medical devices. As appropriate, the PSI and IMB agree to engage in ongoing discussion, consultation, collaboration and review with respect to all matters pertaining to the sale and supply of

medicinal products of mutual concern to either body, having regard to the prevailing legislative, regulatory and administrative frameworks of each body at a particular time.

4.3. Collaboration in the area of Controlled Drugs

The safe and lawful supply of medicinal products containing substances controlled by the Misuse of Drugs Regulations 1988-2007 as amended from time to time is of concern to the PSI and IMB in the public interest. The PSI and the IMB undertake to co-operate and collaborate as appropriate in ensuring the safe and lawful supply, possession and custody of such controlled drugs in the State. This includes undertaking joint initiatives as determined and agreed on a case-by-case basis by the appropriate persons in each body and the sharing of relevant information and details. These joint initiatives may also involve the participation of the Department of Health and Children, An Garda Síochána and the Revenue and Customs Service.

5. 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 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 the safe and effective use of medicines, medical devices and controlled drugs within the practice of pharmacy.

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 or animal health.

Such criteria shall take into account the requirements of the Freedom of Information and Data Protection Acts.

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 the IMB and the PSI as outlined below will not be provided to third parties:

1. In the case of the IMB providing information to the PSI, to investigate, bring criminal and/or fitness to practise proceedings against individuals or

organisations for a suspected or alleged breach of the Pharmacy Act 2007 or any other relevant legislation.

2. In the case of the PSI providing information to the IMB, to investigate, bring criminal proceedings against or take any other action against any individual or organisation for a suspected or alleged breach of the Irish Medicines Board Acts 1995 and 2006 or any other relevant legislation.

5.5 Provision of information will be considered on a case by case basis and in the interests of public and animal 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. Communication and other issues

6.1 The PSI and the IMB 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 authorisation, manufacturing, wholesaling, sale and supply of medicinal products and market surveillance of medical devices in the State. To this end, both bodies are committed, where relevant, to sharing and working together on the provision of guidance for pharmacists, 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) and medical devices are fully understood and complied with.
2. Promoting the recognition and reporting of adverse reactions to medicinal products and adverse incidents with medical devices.
3. Promoting the reporting of quality defects in medicinal products and medical devices.
4. Promoting knowledge and understanding of all matters concerning the sale and supply of unauthorised medicines.
5. Disseminating notifications of recalls and urgent cautionary information relating to medicinal products and medical devices to retail pharmacy businesses
6. Developing information systems that will permit ready access to data relating to individual medicinal products.
7. Maintaining a high level of awareness of the threat posed to public and animal health by counterfeit medicinal products and medical devices and promotion of reporting where there are suspicions.

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 the IMB 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. Legislation

7.1 Both the PSI and IMB, at the request of the Department of Health and Children, 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, include the other in the process of consultation on proposals for new or amended legislation that is of mutual interest and concern.

8. Meetings

8.1 In light of the range of issues of mutual concern to the PSI and the IMB, 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. 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.

Pat O'Mahony	Chief Executive	20/01/09
Signed on behalf of the IMB	Position	Date
	RI/CEO	20/1/09
Signed on behalf of the PSI	Position	Date

Appendix A

IMB List of Main Contacts

Name:	Position:	Contact No.	E-mail address:
Mr. Pat O'Mahony	Chief Executive	6343437	pat.omahony@imb.ie
Ms. Ann O'Connor	Director of Human Products Authorisation and Registration	6343424	ann.oconnor@imb.ie
Dr. J. Gabriel Beechinor	Director of Veterinary Medicines	6343310	jgb@imb.ie
Dr. Joan Gilvarry	Director of Human Products Safety Monitoring	6343371	joan.gilvarry@imb.ie
Mr. John Lynch	Director of Compliance	6343321	john.lynch@imb.ie
Ms. Rita Purcell	Director of Finance and Corporate Affairs	6343438	rita.purcell@imb.ie
Ms. Suzanne McDonald	Director of IT and Change Management	6343411	suzanne.mcdonald@imb.ie
Ms. Frances Lynch	Director of Human Resources	6343439	frances.lynch@imb.ie
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Dr. Caitríona Fisher	Quality Manager	6343420	caitriona.fisher@imb.ie

PSI List of Main Contacts

Name:	Position:	Contact No.:	E-mail address:
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Ms. Kate O'Flaherty	Head of Communications and Public Affairs	2184012	kate.oflaherty@pharmaceuticalsociety.ie
Ms. Damhnait Gaughan	Head of Standards and Practice	2184001	damhnait.gaughan@pharmaceuticalsociety.ie
Mr. John Bryan	Head of Inspection and Enforcement	2184014	john.bryan@pharmaceuticalsociety.ie
Ms. Sinead O'Keeffe	Deputy Head of Administration and Finance	2184006	sinead.okeefe@pharmaceuticalsociety.ie
Ms. Marita Kinsella	Head of Legal Affairs	2184013	marita.kinsella@pharmaceuticalsociety.ie