



Preliminary Overview - Pharmacy Act 2007

A New Beginning



PSI

THE PHARMACEUTICAL
SOCIETY OF IRELAND

Cumann Cógaiseoirí na hÉireann

THE PHARMACY REGULATOR

PREFACE

The Minister for Health and Children, Mary Harney TD, pursuant to the Pharmacy Act 2007, has appointed the Council of the new Pharmaceutical Society of Ireland. The new Pharmaceutical Society of Ireland is the regulator for Pharmacy in Ireland. The Council of the new Pharmaceutical Society of Ireland will commence its work in partnership with the Department of Health and Children and all stakeholders to facilitate the successful implementation of this legislation on an incremental basis.

The principal functions and responsibilities of the pharmacy regulator are to;

- Protect patients and the public interest
- Maintain Registers of pharmacists and pharmacies
- Inspect pharmacy practices and enforce pharmacy legislation
- Draw up Codes of Conduct for pharmacists and pharmacy owners and oversee the quality assurance and application of best practice across the sector
- Promote and ensure high standards of education and training including continuing education in pharmacy
- Conduct inquiries to determine 'fitness to practise' and 'fitness to operate'
- Process complaints relating to pharmacy practice and operation
- Act as the registration authority for pharmacists outside of Ireland and the EU
- Act as the Competent Authority for recognition of qualifications from other EU countries

This will ensure the safe delivery of pharmacy services in a safe environment, requiring all involved in such care provision to meet the highest standards of care, treatment and service. The new Pharmaceutical Society of Ireland is accountable directly to the Minister for Health and Children and committees of the Oireachtas.

This is an overview and general guide only. It is not a legal document and does not have legal effect. This guide aims to provide a high level overview of the Pharmacy Act 2007 as it is not yet possible to provide detailed information on every aspect of this legislation. This guide is produced as an integral part of the new Pharmaceutical Society of Ireland's commitment to developing as a high performing regulator that responds to the needs of patients, the public, the profession of pharmacy, pharmacy owners and the wider healthcare sector.

The Pharmacy Act 2007 is an essential piece of legislation that provides for the health, safety and welfare of patients and the public. It will be introduced on a phased or incremental basis by the Minister for Health and Children. It will enable pharmacists to practise in a regulated, controlled and safe environment in a manner which will ensure the provision of high quality treatment, meeting the challenges of increasingly complex and evolving care and therapeutic regimens for patients. It will provide a system whereby pharmacy owners will be facilitated in ensuring responsible and accountable practices whilst providing the highest level of patient care and service.

The new Pharmacy Regulator looks forward to further collaboration, consultation and dialogue involving patients, their advocates, pharmacists, pharmacy owners and schools of pharmacy. The new Council will set out a full implementation programme following consultation. They will seek to work in partnership, and collaborate at the highest level, with all stakeholders.

Dr. Ambrose McLoughlin
Registrar

WHAT DOES THIS LEGISLATION MEAN FOR MEMBERS OF THE PUBLIC?

The profession of pharmacy evolved and exists to serve the health needs of the public. The new Pharmacy Regulator was created to protect, maintain and promote the health and safety of the public. This means that pharmacists, and the owners of the pharmacies within which they practice, will be fully accountable to an independent statutory authority which in turn is accountable to the Minister for Health and Children and committees of the Oireachtas.

The new Regulatory body will publish a full Register of pharmacists and pharmacies online and in one other form on an annual basis. A Certificate of Registration will also be issued to each pharmacist and each pharmacy owner. These certificates must be displayed in the pharmacy at all times. This will allow patients and members of the public to identify that their local pharmacist/pharmacy is registered with the Pharmacy Regulator.

Any complaints or disciplinary matters arising will be dealt with by the new Pharmacy Regulator. A comprehensive, independent complaints procedure will be put in place. Any complaint made will be considered in detail and where necessary appropriate remedial action taken. The regulator will ensure that each pharmacist must be 'fit to practise' on an annual basis and all pharmacies must be 'fit to operate' on an annual basis.

The Pharmacy Regulator will advise the Minister, the Department of Health and Children, other Statutory Agencies and the public of matters they deem to be in the public interest e.g. the suspension of a registration of a pharmacist or pharmacy owner or the closure of a pharmacy.

For the first time all pharmacists will be subject to fitness to practise provisions with full professional accountability. In addition following consultation with pharmacists, a new code of professional conduct for pharmacists and pharmacy owners will be put in place and enforced.

The Pharmacy Act 2007 introduces regulatory provisions which will have important implications for pharmacy owners. Regulation of the environment in which pharmacy service and care is provided, protects public health and wellbeing. The Pharmacy Regulator will be responsible for the maintenance of a register of all retail pharmacy businesses, as defined under the Act.

Fitness to operate provisions will apply with an independent complaints system which provides a mechanism to address the accountability and responsibilities of pharmacy owners. Pharmacies will be inspected regularly, routinely and thoroughly. Delivery of high quality and safe pharmacy care will be the primary objective of the new system.

THE NEW PHARMACEUTICAL SOCIETY OF IRELAND

The Pharmacy Act 2007 dissolves the old Pharmaceutical Society of Ireland and establishes the new Pharmaceutical Society of Ireland as regulator of pharmacy in Ireland. All pharmacists will be required to be registered with the new Pharmaceutical Society of Ireland, which will act by and through the Council.

COUNCIL OF THE PHARMACEUTICAL SOCIETY OF IRELAND

Who will be on the Council of the new Pharmaceutical Society of Ireland?

The Council of the new Pharmaceutical Society of Ireland will be composed of twenty one persons appointed by the Minister for Health and Children. The President and Vice President of the Council will be registered pharmacists. The Council will be composed of nine elected pharmacists, one additional registered pharmacist nominated by the Schools of Pharmacy and eleven non-pharmacists who will be appointed by the Minister for Health and Children. The term of office will normally be four years. The first Council will be composed of the eleven Ministerial nominees, the School's nominee and nine pharmacists selected by the outgoing Council. However, after a period of two years eleven members of the first Council, drawn by lot, will retire. Five of these must be pharmacists and six will be non-pharmacists. These eleven will be replaced by five new pharmacists and six new non-pharmacists.

How will the Council carry out its functions?

The Registrar and corporate management team will be responsible and accountable for the management and control of the day to day affairs of the Regulator. There are some functions and matters which may only be carried out by the Council.

Council will have a number of committees, some of which are specified in the Act, such as the Disciplinary Committees and others which will be established to assist the Council in performing its functions. Committee members may be drawn from outside of the Council membership. The Council will appoint a chair of each Committee. Committee meetings will be held independently of Council who will meet at least four times a year.

GOVERNANCE

What governance requirements will apply to the Pharmacy Regulator?

The new Pharmaceutical Society of Ireland is a regulatory body under the aegis of the Department of Health & Children and as such it must comply in full with the Framework for Corporate and Financial Governance as set down by that Minister and that Department in April 2006. This framework establishes minimum standards of best practice relating to the guiding principles, structures, codes of conduct, reporting, compliance and accountability. The Department requires the Pharmacy Regulator to be guided by this framework as it establishes its governance procedures. The Minister, the committees of the Oireachtas, the Department and the Comptroller and Auditor General will expect the Pharmacy Regulator to continually evolve its procedures and structures to remain in line with evolving international best practice in governance. The Pharmacy Regulator must also comply with the specific directions of the Minister for Finance where appropriate.

REGISTERING PHARMACISTS AND PHARMACIES

Why must Pharmacists and Pharmacies be registered?

In the interests of public protection, all pharmacists who wish to practise in Ireland must be registered with the Pharmaceutical Society of Ireland. The purpose of registration is to ensure that all pharmacists practising in Ireland have the necessary education, qualifications and training and are fit and proper persons to provide safe and effective pharmacy care and treatment to patients.

All pharmacies in Ireland must also register with the Pharmacy Regulator in the public interest. The purpose of this is to ensure that all pharmacies have, for example, the necessary staff, facilities, equipment, procedures etc. to provide safe and effective pharmacy care to patients.

The new Pharmaceutical Society of Ireland will be required to keep a Register of Pharmacists, and other pharmacy staff such as, druggists and pharmaceutical assistants. Also, all pharmacies will be required to be registered in the Register of Retail Pharmacy Businesses.

The Pharmacy Regulator will stand over the integrity, probity and safety of all of its registration systems for both pharmacists and pharmacies, in order to ensure that it properly performs its statutory role in the protection of public health, welfare and safety.

REGISTERING OF PHARMACISTS

What are the routes of registration that will apply?

The Pharmacy Act 2007 makes provision to allow for a number of different registration routes;

- Registration of individuals who have qualified in Ireland
- Registration of individuals who have qualified in the EU/European Economic Area
- Registration of individuals who have qualified in states other than the above

The individual must hold the qualification required for practice and have completed the prescribed training and education.

How often will pharmacists have to register and will they have to pay a fee?

Pharmacists must register annually. All pharmacists must be 'fit to practise' prior to having their registration renewed and Certificate of Registration issued each year. A fee will apply with non payment of this fee resulting in removal from the register.

Will the Register be public and what information will be displayed relating to each pharmacist?

The Register of Pharmacists will be published annually both online and in one other form. Information published will include the name of the pharmacist and other prescribed information. The rules of the Data Protection legislation 1988-2003 will apply to the affairs of the Regulator.

REGISTERING OF PHARMACIES

How often will pharmacies have to register and will a fee apply?

Registration of pharmacies will be similar to that of pharmacists with initial registration and continuing registration taking place annually. All pharmacies must be deemed 'fit to operate' prior to having their registration renewed. A Certificate of Registration will be issued each year. A registration fee will apply. Any entity ceasing to be registered must return the Certificate of Registration within 14 days to the Registrar.

Will the register be in the public domain and what information will be displayed relating to each pharmacy?

The register of pharmacies will be published annually both online and in one other form. The rules of the Data Protection legislation 1988-2003 will apply. Information to be supplied by an owner wishing to register as a retail pharmacy business will include;

- the name under which the pharmacy will operate
- the address of the premises where pharmacy services will be delivered
- the names and ownership details of the pharmacy
- the name of the pharmacist who will supervise the pharmacy

COMPLAINTS

This legislation has made provision for a new, comprehensive, independent complaints procedure. Outlined below are some of the main elements which will feature in this system

How can complaints be made?

Anyone can file a complaint with the new Pharmaceutical Society of Ireland relating to a pharmacist or a pharmacy. This complaint must be made in writing or, if this is not possible, in a form that is agreed upon by the Council of the new Pharmaceutical Society of Ireland. Similarly a complaint can be made on behalf of any person by the Registrar. Where a complaint relates to other professions the Pharmacy Regulator is empowered to work with other statutory agencies in the public interest and to protect patient safety.

What happens once a complaint has been received?

Firstly the complaint will be registered. The pharmacist or pharmacy owner about whom the complaint has been made will be informed of this fact and receive a copy of the complaint. All complaints will then be forwarded to the Preliminary Proceedings Committee (PPC) whose function it is to assess, through further investigation, whether there is sufficient cause to warrant further action. Once the assessment is complete the PPC advises the Council of its findings.

What happens if a complaint is deemed to require no further action?

In this case the Council shall inform the pharmacist or pharmacy owner, the complainant and the PPC accordingly.

What happens if a complaint is deemed to require further action?

A number of things may happen at this stage, the complaint may be referred for resolution by mediation, the matter may be referred to the Professional Conduct Committee (PCC) or to the Health Committee for further investigation.

Is there a mechanism where complaints can be addressed in a less formal manner?

The Act provides for the ability to address complaints through a Mediation Process. The regulator will prepare guidelines to facilitate this process. Such a mechanism will only function if both the complainant and the pharmacist/pharmacy owner in question is willing to proceed. Use of mediation will not prohibit the use of the other aspects of the complaints mechanism if that is required, however any information obtained through the mediation process may not be used in the disciplinary process.

FITNESS TO PRACTISE & FITNESS TO OPERATE

In order to ensure that standards of professional conduct and practice are continuously maintained, this legislation provides for the assessment of a pharmacist's 'fitness to practise' as well as a pharmacy owner's 'fitness to operate'

How will 'fitness to practise' work?

All pharmacists wishing to register or renew their registration with the new Pharmacy Regulator will have to be 'fit to practise'. Compliance with a number of factors, determined by the Council, will have to be evidenced in order to meet the standard. This is essential to ensure that the public are provided with pharmaceutical care and services by an individual competent to do so.

How will 'fitness to operate' work?

All pharmacy owners wishing to register or renew their registration with the Pharmacy Regulator will have to be 'fit to operate'. Those who wish to register must fulfill and comply, on an annual basis, with regulations to be made by the Minister so that the activity of retail pharmacy businesses will be carried out in a safe, proper and compliant manner.

Once a person is deemed 'Fit to Practise' or 'Fit to Operate' can this be called into question prior to their next renewal?

Through the new complaints system it is possible that a pharmacist previously deemed 'fit to practise' or a pharmacy owner previously deemed 'fit to operate' may have cause to appear before a committee of inquiry to answer a complaint made against them. If a committee of inquiry finds a pharmacist no longer 'fit to practise' or a pharmacy owner no longer 'fit to operate' their certificate of registration can be revoked or their continuing practice may have conditions placed upon it.

Will the Pharmacy Regulator make public its findings in respect of serious complaints upheld against pharmacists or pharmacies?

Where the Council determines that a pharmacist is unfit to practise or a pharmacy is unfit to operate or that certain sanctions are imposed, the details will be published by the Pharmacy Regulator in accordance with the legislation.

INSPECTION

The new Pharmaceutical Society of Ireland, will have significant and important inspection and enforcement powers afforded to it by the Act to strengthen its role in protecting patient safety and the public.

Why is it necessary for the Pharmacy Regulator to have Inspection and Enforcement powers?

The general purpose of the inspection process and the function of the Inspectorate is to ensure that all pharmacies operating in the State are compliant with the law and best practice. Inspectors of pharmacies will focus on the assessment of compliance with legislation, guidance issued by the Council of the Pharmacy Regulator and approved codes of conduct.

Must pharmacies cooperate with the Pharmacy Regulator's Inspectorate?

Yes. The Pharmacy Act 2007 obliges all pharmacists and pharmacy owners to cooperate with an Inspector appointed by the Pharmacy Regulator. Inspectors will be issued with a warrant of appointment which will enable them to enter and remove evidence from any pharmacy practice at all reasonable times.

Similarly inspectors will also be empowered to enter and remove evidence from a private residence once invited or if in possession of a warrant. Pharmacy owners and others are, in certain circumstances, obliged to answer questions put to them by an Inspector.

Can an Inspector of the Pharmacy Regulator require a pharmacy owner to close their pharmacy?

To ascertain whether an offence has been committed under the Act an Inspector may, if necessary, secure for later inspection any pharmacy or part of any pharmacy for a reasonable period of time to enable him to carry out his function.

What are the possible outcomes of an inspection under the Pharmacy Act 2007?

A number of outcomes are provided for under new legislation. In the case of pharmacy care that is being delivered in a manner that is compliant with the relevant legislation no further action will be taken. However, in the case of pharmacies where there is obvious and evident non-compliance there are a number of possible scenarios including re-inspection, referral to a committee of inquiry, restrictions placed on the practice or prosecution and subsequent closure if approved by the courts.

FREQUENTLY ASKED QUESTIONS

Will the new Pharmacy Act apply immediately?

The Pharmacy Act 2007 will be implemented in stages. This will allow for a smooth transition.

Will the old Pharmaceutical Society of Ireland still exist?

Under the Pharmacy Act 2007 the old Pharmaceutical Society of Ireland has been dissolved and been replaced with a new body known as 'The Pharmaceutical Society of Ireland (The Pharmacy Regulator).

Will I still be registered with 'The Pharmaceutical Society of Ireland'?

Yes. All pharmacists currently registered will be entitled to use the letters MPSI after their name. The categories of LPSI and FPSI will no longer exist.

Will the Council comprise solely of pharmacists?

No. There will be a lay majority on the Council of the Pharmaceutical Society of Ireland. Both the President and Vice-President of the Council will be pharmacists.

Can complaints be addressed in public hearing?

Hearings before the Professional Conduct Committee will be held in public however, there is provision within the legislation for the hearings to be heard in private if such a request is made and the PCC deem it appropriate.

Hearings before the Health Committee will be held in private, however there is provision within the legislation for the hearings to be heard in public if such a request is made and the committee deem it to be appropriate.

Will the findings of the Professional Conduct Committee or the Health Committee be made public?

There is provision within the Pharmacy Act 2007 for such findings to be made public if they are in the public interest. However, there is also provision for the findings of these committees to remain unpublished.

Will the Council of the Pharmaceutical Society of Ireland be able to remove a person from the register?

The Council of the Pharmaceutical Society of Ireland may make an application to the High Court for the cancellation of the pharmacist's registration. The pharmacist may appeal such an application to the High Court.

CHECKLIST

Will the Council be able to make rules and regulations?	YES
Will the Council be able to delegate any of its functions to committees?	YES
Will the Pharmaceutical Society of Ireland keep registers of pharmacists?	YES
Will everyone on the register of pharmacists be automatically transferred?	YES
Will all pharmacies have to be registered?	YES
Does a certificate of registration have an expiry date?	YES
Is the use of the title 'pharmacist' and 'pharmacy' prohibited if you are not entitled to use it under the provisions of the Act?	YES
Can pharmacists/pharmacy owner's registration be cancelled for non payment of registration fees?	YES
Will the Minister lay down the standards for retail pharmacy businesses?	YES
Does a pharmacist have to be present whenever a retail pharmacy business is in operation?	YES
Does the Act provide for inspection of all pharmacies?	YES
Does Fitness to Practise apply to all pharmacists irrespective of pharmacy work environment?	YES
Can an Inspector visit any pharmacy work environment to investigate a complaint against a pharmacist?	YES
Can a pharmacist be struck off the register?	YES
Do I need three years experience in a retail pharmacy business to be a supervising pharmacist	YES
Is experience in another jurisdiction taken into account when deciding on ability to be a supervising pharmacist?	YES
Can a complaint be made against a pharmacy business?	YES
Can a non- registered pharmacist be asked to account for an issue that occurred when he/she was registered and practising?	YES
Can a person be a member of more than one of the disciplinary committees concurrently?	YES
Do I have to attend a hearing if asked to do so by a Committee of Inquiry?	YES
Is there a right of appeal against the findings of a fitness to practise inquiry?	YES



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