

# Pharmaceutical Society of Ireland - Role of the regulator

Education and Registration Dept. PSI  
September 2017



THE PHARMACY REGULATOR

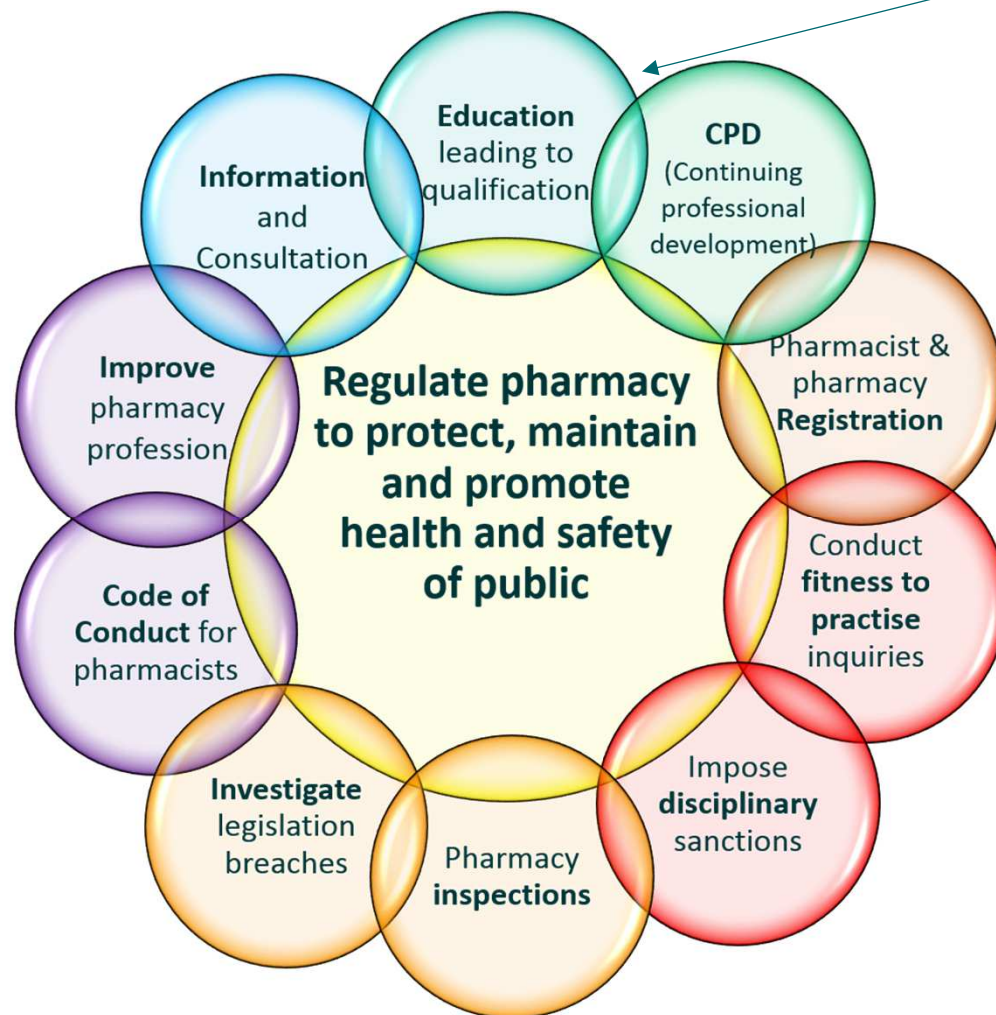
# Outline

- 1. Role of the Pharmacy Regulator (PSI) - Education**
- 2. Changes in Pharmacy Education in Ireland – regulatory context**
- 3. Accreditation – regulatory perspective**
- 4. CPD**

# 1. Role of the Pharmacy Regulator (PSI) Pharmacy Act 2007



# Pillars of regulation



# Pharmacy Act 2007

## Functions of the PSI

- ▶ Regulate pharmacy to protect, maintain and promote public health and safety
- ▶ **Promote and ensure high standard of education and training of pharmacists**
- ▶ **Ensure that pharmacists obtain appropriate experience**
- ▶ Ensure that pharmacists undertake appropriate continuing professional development (CPD), including the acquisition of specialization.
- ▶ Supervise compliance with this Act and the instruments made under it,
- ▶ Supervise compliance by pharmacists with Chapters 2 and 3 of Part 2, and Part 3, of the Health (Pricing and Supply of Medical Goods) Act 2013.”,

## Quick overview - Where we are now


- Progress on evolving pharmacy education in Ireland
  - Vision for quality and performance – delivering for the public
  - Engagement & partnership model in design and delivery with HEI's
  
- PSI supporting professionalism & ongoing development
  - Extensive practice development & CPD supports are now in place
  - Practice Guidance from PSI
  - CPD support from IIOP

## 2. Pharmacy Education in Ireland - regulatory context



## Directive 2005/36/EC

- ▶ Article 44 (formerly Art 2 of 85/432/EEC) specifies the minimal conditions for the awarding of formal qualifications in pharmacy in the EU
- ▶ To qualify as a pharmacist, a person must complete:
  - ▶ **At least a five year course** of studies which must comprise:
    - ▶ A minimum of four years of full-time university-level academic studies (theoretical and practical); and
    - ▶ A minimum of six months practical training in either a community or hospital pharmacy



Legislative  
framework for  
pharmacist  
qualification



# Evolution of Pharmacist Qualification



## PHARMACY EDUCATION AND ACCREDITATION REVIEWS (PEARs) PROJECT

Professor Keith A Wilson  
Dr Christopher A Langley

June 2010

**FINAL REPORT**

The Pharmacy Education and Accreditation Reviews (PEARs) Project was commissioned and funded by the Pharmaceutical Society of Ireland (PSI - the Pharmacy Regulator) in accordance with section 9 of the Pharmacy Act, 2007.

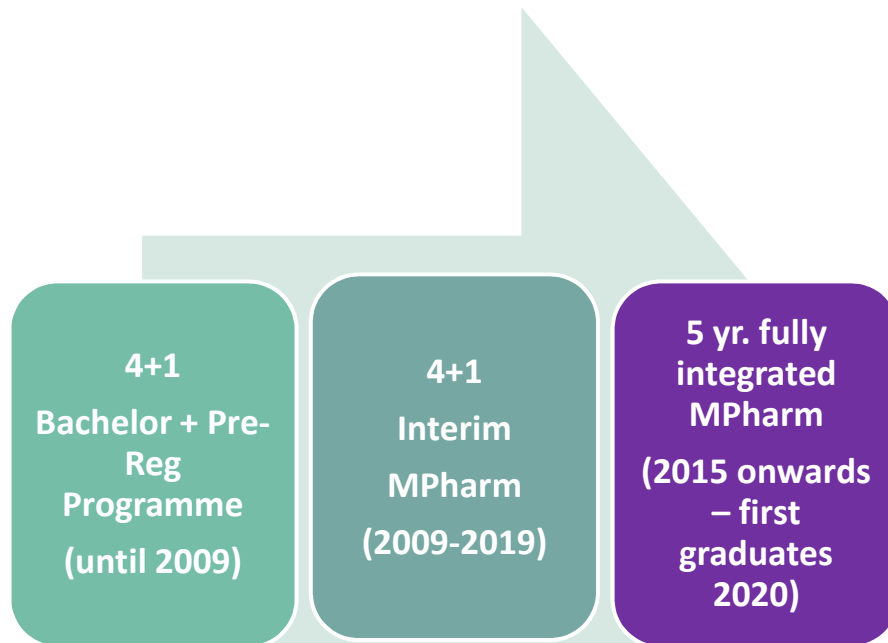


4+1  
Bachelor +  
Pre-Reg  
Programme  
(until 2009)

4+1  
Interim  
MPharm  
(2009-2019)

5 yr. fully  
integrated  
MPharm  
(2015  
onwards –  
first graduates  
2020)

# Five-Year Fully Integrated Master's Degree Programme



- ▶ Qualification for practice from 2020 onwards
- ▶ Aim is to produce more clinically focused pharmacists, who will be positioned to play a critical role in the delivery of future integrated health care services in Ireland
- ▶ Involves the integration of the curriculum to support the dispersal of practice placements throughout the five years
- ▶ Shared service among the Schools of Pharmacy for management of practice placements – [APPEL: Affiliation for Pharmacy Practice Experiential Learning](#)

# Five-Year Fully Integrated Master's Degree Programme -Placement Structure

## Placement Structure for the Five-Year Fully Integrated Masters Degree Programme in Pharmacy

Approved by the PSI Council on 2 October 2014

	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May	June	July	Aug	
Year 1	Standard Academic Time				Standard Academic Time								
Year 2	Standard Academic Time				Dispersed Shadow Placement	Standard Academic Time	Dispersed Shadow Placement	Standard Academic Time	Dispersed Shadow Placement	Standard Academic Time			
Year 3	Standard Academic Time				Standard Academic Time								
Year 4	Standard Academic Time				Statutory Placement	Standard Academic Time							
Year 5	Standard Academic Time				Statutory Placement								Professional Registration Exam
	Semester 1				Semester 2				This period is: Summer for Years 1-3 Start Semester 1 for Year 4 Semester 3 for Year 5				

Key Indicator	
Standard Academic Time	Light Blue
Practice Placements	Dark Blue
Year 4: Sept-Dec. and Year 5: Jan-Aug. are statutory placements	Dark Blue
Denotes dispersed Shadow Placements in Year 2	Dark Red
Denotes Professional Registration Exam after conclusion of 8 month placement	Green

### 3. Accreditation - role of the Regulator



# Accreditation and Approval of programmes

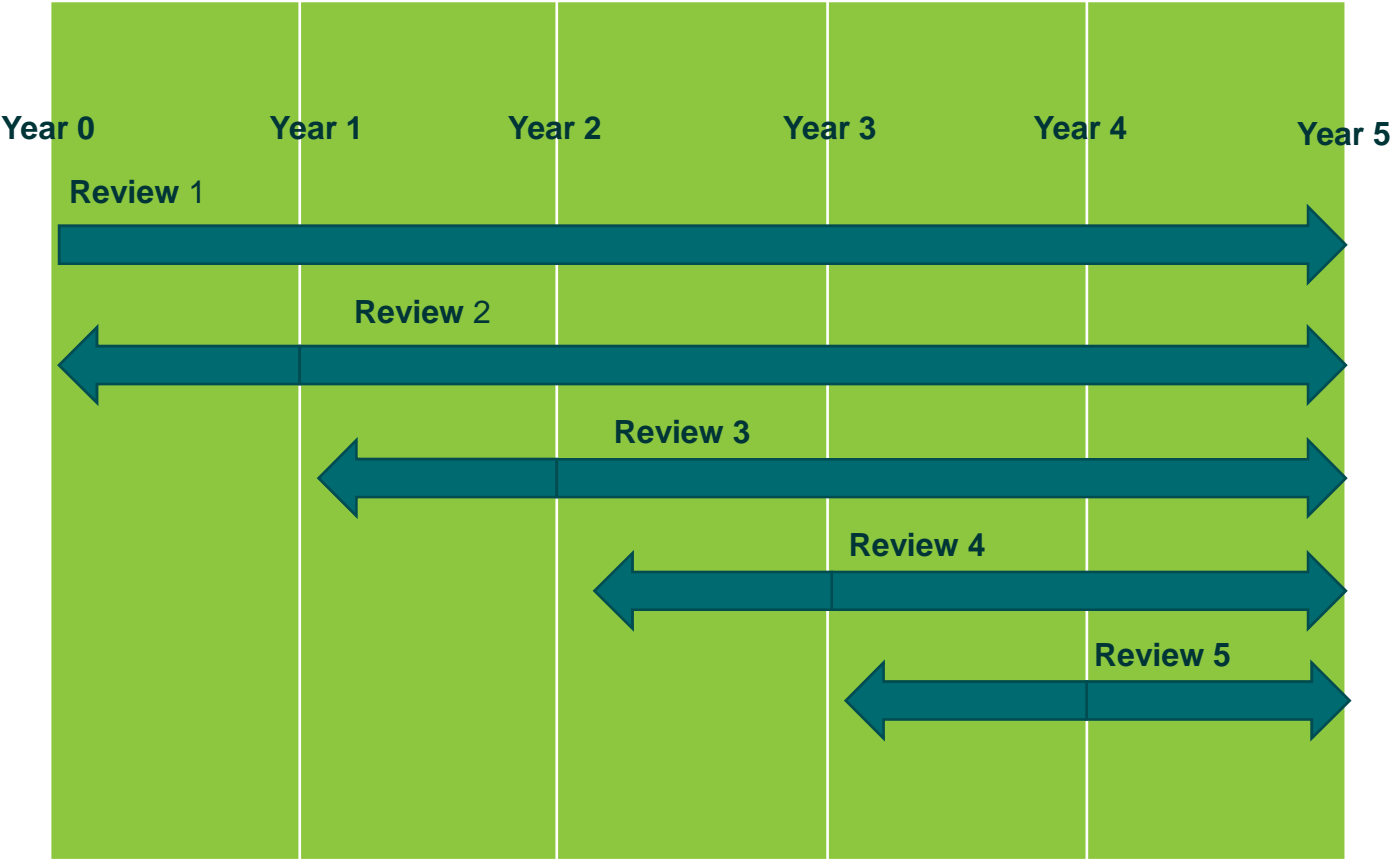
- Accreditation:
  - Standards developed based on review of international experience and best practice
  - Graduates of an accredited programme – attain the ‘qualification appropriate for practice’ as a criterion for eligibility to apply to register



# Accreditation Standards - Integrated MPharm

- ▶ **Standard 1:** The Professional Degree Programme Provider & Mission
- ▶ **Standard 2:** Leadership, Organisation and Governance
- ▶ **Standard 3:** Resources
- ▶ **Standard 4:** Curriculum
- ▶ **Standard 5:** Teaching & Learning Strategy
- ▶ **Standard 6:** Assessment Strategy
- ▶ **Standard 7:** Quality Assurance & Enhancement
- ▶ **Standard 8:** Students

# Scope of accreditation reviews over the course of the establishment of Integrated MPharm programme



# Accreditation Team

## Composition of the Accreditation Team

Accreditation Team Chair

Healthcare non-pharmacist member

Patient Advocate/Public Interest/Risk Expert

Pharmacist Practising in Ireland

Accreditation / HEI Quality Assurance/ Regulatory Expert

Pharmacy Academic with experience of developing and/or accrediting pharmacy degree programmes

Recently qualified pharmacist with 0-3 years post-registration experience



# Accreditation reporting process

First draft of accreditation reports circulated to accreditation team within 2-3 weeks of visit

Draft reports circulated to HEI for review, comment and to correct errors of fact (1 month to review)

Publication of final summary report on PSI website

Receipt of comments from team within 10 working days

Finalised report to:

- PD&L 7 June
- PSI Council 29 June

# Decision Making



Condition

Requirement

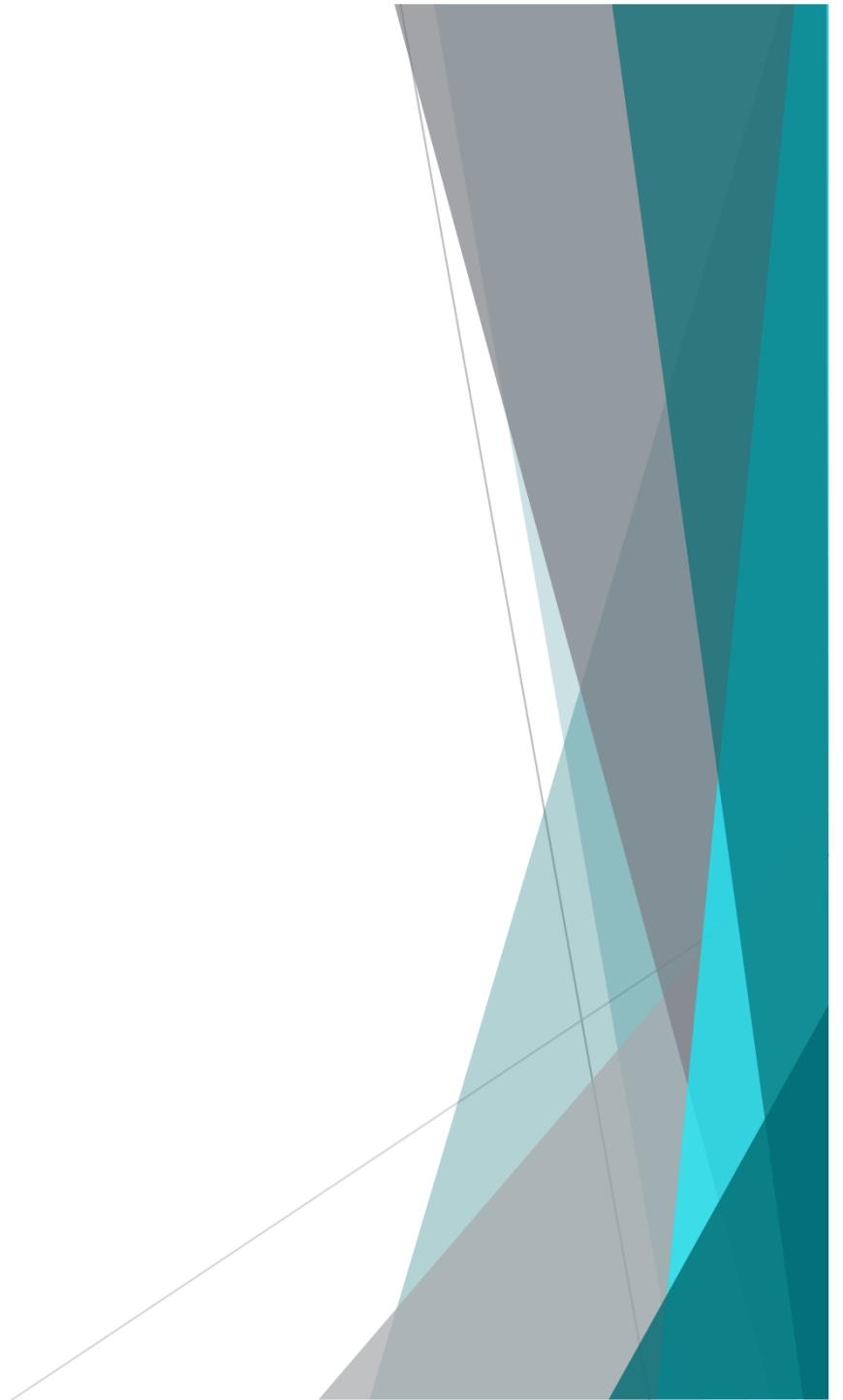
Clarification

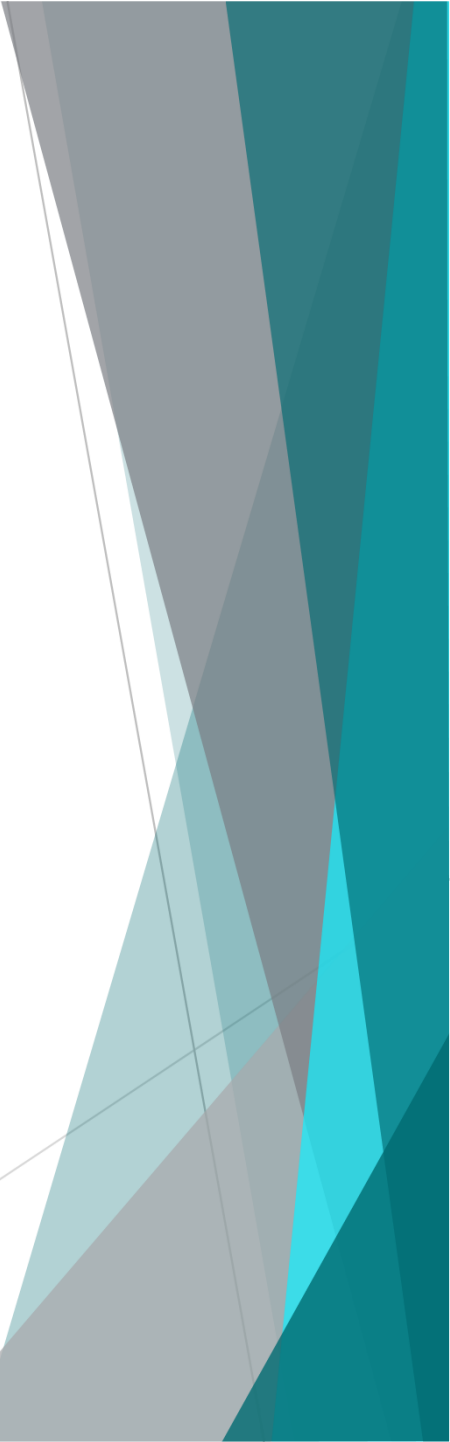
# Inter professional learning

## Standard 4 -Curriculum

4.5 The curriculum must be delivered by **interdisciplinary teams** in order that the subject matter of the degree is integrated, and delivered in a patient-focussed manner. The student must be provided with the knowledge and experience that will facilitate an understanding of the key regulatory and scientific aspects of drug discovery, and the manufacture, preparation, quality control, distribution, actions, interactions and use, including, the evidence-based use, of medicines by patients and including health screening, health promotion, pharmaceutical care and the **inter professional nature** of health and social care services.

## 4. CPD





*CPD- continual process of  
lifelong learning which is  
focused on implementing  
learning in your professional  
practice and improving outcomes  
for patients*

## CPD

- It differs from continuing education (CE) in that it is not based on a traditional points system or accumulation of contact hours.
- It represents a more **flexible approach** to learning and recognising a wide variety of learning activities from formal learning to on-the-job learning.
- It is a **self-directed learning** process based on a 5-stage CPD cycle which includes: self-appraisal; planning; action; documentation and evaluation.
- It involves **reflective practice** with pharmacists required to reflect on individual experience to identify learnings or how they might need to improve their knowledge, skills, behaviours or attitudes (i.e. competence).
- It is a structured process which requires **recording and reflection** at all stages of the CPD cycle e.g. recording of learning needs, documentation and evaluation of learning outcomes, identification of actions to enhance practice.

# Irish Institute of Pharmacy

**IIOP**  
INSTITIÚID CÓGAI SIÓCHTA NA HÉIREANN  
IRISH INSTITUTE OF PHARMACY

THE PROFESSION   PRACTICE & RESEARCH   COURSES & EVENTS   MY INSTI

## MANAGING QUALITY IN PHARMACY PRACTICE

Provided by: **iaCME**

*Our on-line Managing Quality in Pharmacy Practice course aims to introduce pharmacists to recognised principles of quality improvement. Following the completion of the on-line component, you will have the option to enrol on a one day face to face programme which focuses on application of learnings to quality improvement in the supply of high-risk medicines.*

Provided by: **iaCME**

The Irish Institute of Pharmacy's (IIOP) role includes the development and implementation of a CPD system for pharmacists in Ireland and the development of pharmacy practice in line with international best practice and evolving healthcare needs.

The Institute will support pharmacists to engage with CPD and will commission education and training programmes in line with national policy.

Education  
Competence



Domain	Competency
Professional practice	<ul style="list-style-type: none"> <li>Practises 'patient-centred' care</li> <li>Practises professionally</li> <li>Practises legally</li> <li>Practises ethically</li> <li>Engages in appropriate continuing professional development</li> </ul>
Personal skills	<ul style="list-style-type: none"> <li>Leadership skills</li> <li>Decision-making skills</li> <li>Team working skills</li> <li>Communication skills</li> </ul>
Supply of medicines	<ul style="list-style-type: none"> <li>Manufactures and compounds medicines</li> <li>Manages the medicines supply chain</li> <li>Reviews and dispenses medicines accurately</li> </ul>
Safe and rational use of medicines	<ul style="list-style-type: none"> <li>Patient consultation skills</li> <li>Patient counselling skills</li> <li>Reviews and manages patient medicines</li> <li>Identifies and manages medication safety issues</li> <li>Provides medicines information and education</li> </ul>
Public health	<ul style="list-style-type: none"> <li>Population health</li> <li>Health promotion</li> <li>Research skills</li> </ul>
Organisation and management skills	<ul style="list-style-type: none"> <li>Self-management skills</li> <li>Workplace management skills</li> <li>Human resources management skills</li> <li>Financial management skills</li> <li>Quality assurance</li> </ul>

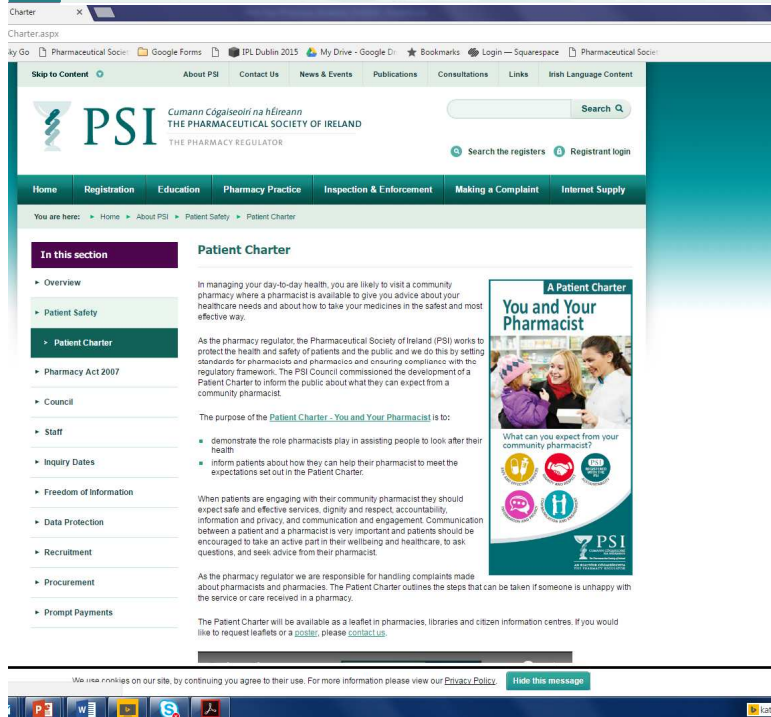


## The Roles and Responsibilities of the Supervising Pharmacist

To promote an understanding of the roles and responsibilities of a supervising pharmacist, the requirement, governance and accountability aspects of the role, the PSI has developed a video series.



# Thank you!



The screenshot shows the PSI website's Patient Charter page. The header includes the PSI logo and navigation links. The main content area features a sidebar with a table of contents and a main text area with a video player. The table of contents lists sections such as Overview, Patient Safety, Pharmacy Act 2007, Council, Staff, Inquiry Dates, Freedom of Information, Data Protection, Recruitment, Procurement, and Prompt Payments. The main text area contains an introduction to the Patient Charter, its purpose, and a list of key points. A video player is embedded in the text, showing two women in a pharmacy setting.

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Website: [www.psi.ie](http://www.psi.ie)