The Pharmaceutical Society of Ireland

Learning Event Sessions 2014

Welcome and Introductions

Role of the PSI

- Pharmacy Act 2007 requires PSI to:
  - Protect the health and safety of the public by regulating the profession of pharmacy and pharmacies
  - Take action to improve the profession of pharmacy
- Scope of PSI's remit:
  - 5285 pharmacists
  - 452 pharmaceutical assistants
  - 1837 retail pharmacy businesses
- 21 member Council – majority non-pharmacists
- Significant programme of work since 2007 to meet obligations under Pharmacy Act

How does the PSI do its job?

Area	Key activity
Education and training of pharmacists	M Pharm – new 5 year integrated degree 2015
Registration	Registers of pharmacists, pharmaceutical assistants, retail pharmacy businesses Superintendent / supervising pharmacists
Maintenance/ development of competence post-registration	Mandatory CPD – Institute of Pharmacy (IIOP)
Promote high standards of practice	Code of Conduct, regulations & rules, guidelines, advice, peer support
Inspection & enforcement	Pharmacy inspections, enforcement activity, Review of inspection policy 2014
Fitness to practise	Fitness to practise procedures
Improve the profession	Institute of Pharmacy, Pharmacy 2020 Supporting new roles, e.g. vaccination, EHC

Why Regulate the Profession?

- Essential for professions involved in irreversible care and treatment of patients e.g. doctors, dentists, nurses, pharmacists

- Requires and enables professionals to practise their profession in a controlled and safe environment, focussed on the safety and interests of their patients

- Protects public health by ensuring that practitioners are trained, qualified and competent within their scope of practice

- Clear declaration of standards expected of the profession

- Maintains public confidence in the profession

# Principles that Underpin Regulation

- Serving and protecting the public interest
- Safeguarding patient welfare
- Promoting patient protection
- Promoting risk assessment and mitigation

And … balancing this public interest protection with fairness to the practitioner

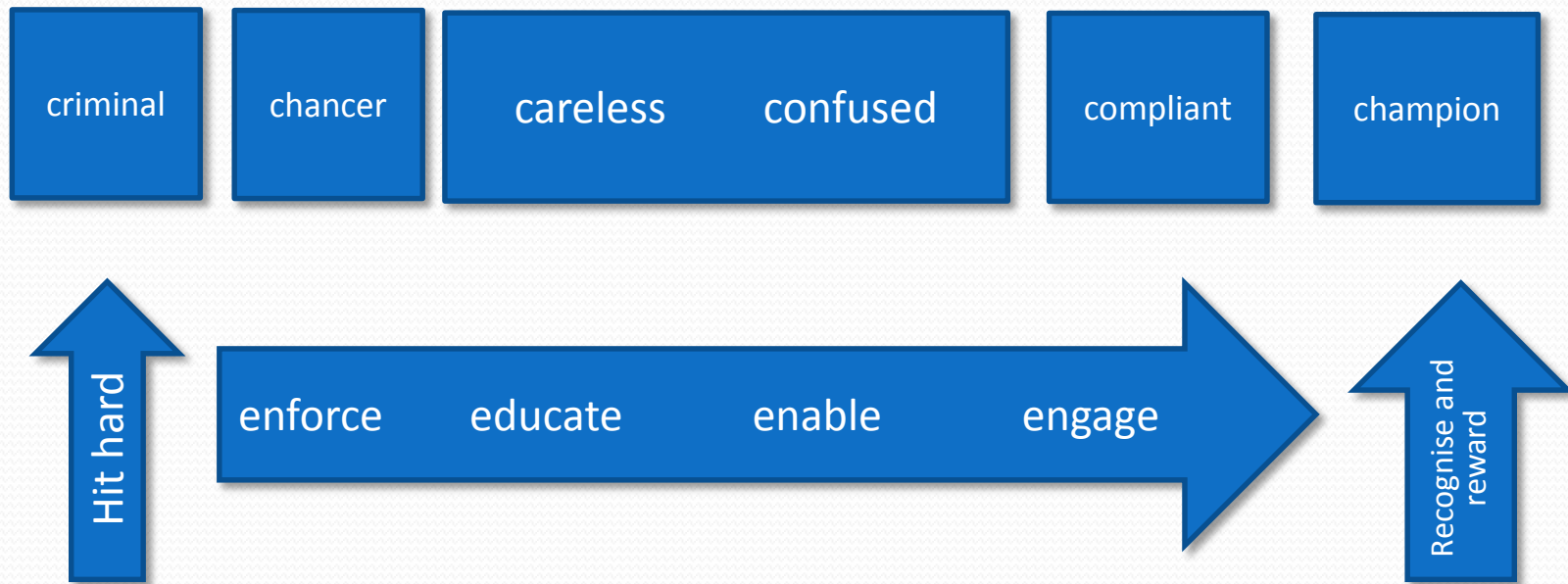# Getting the Balance Right in Regulation

Regulator-driven
Disciplinary action
Inspection
Enforcement etc.
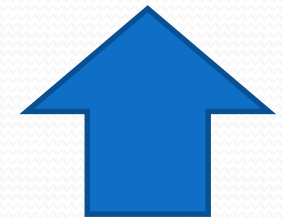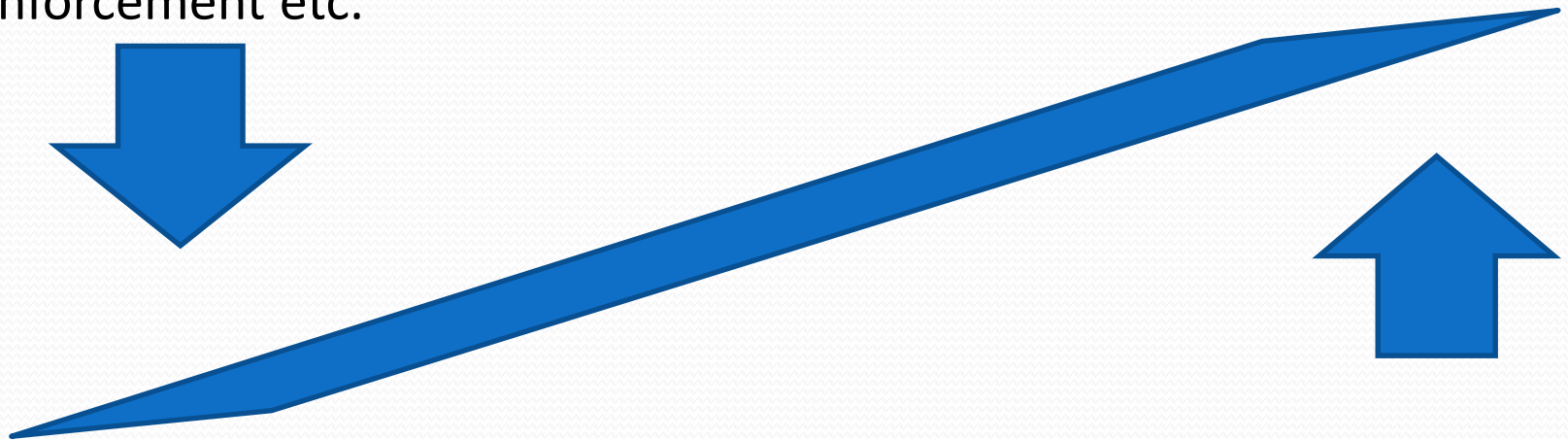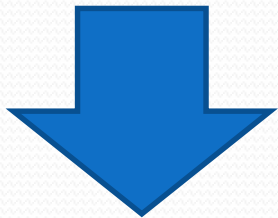
Practitioner-driven
Quality management
Self-audit
Learning from errors etc.

Real World - Target Regulation

criminal

chancer

careless   confused

compliant

champion

Hit hard

enforce   educate   enable   engage

Recognise and reward

Professor Campbell Gemmell CEO SEPA

Context of Learning Events

- PSI educating, enabling and engaging with the profession

- Content based on survey of profession earlier this year to identify what pharmacists wanted to hear about in relation to Inspection and Enforcement and Fitness to Practise

Common themes

- Inspection and Enforcement
  - Focus of inspections
  - Recurrent problems
  - How an inspection progresses
  - Inspection policy
  - Resources – quality systems implementation, SOP's

- Fitness to Practise
  - Life Cycle of a complaint
  - Use of information
  - "Fit to practise"
  - Code of conduct

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**Session One
Inspection and Enforcement**

Introduction

1. Inspection

- Format of inspection on the day
- Different types of inspection
- What happens after inspection?

2. Investigation

- Why does an investigation happen?
- What does it involve?
- What happens afterwards?

# The Inspection Process

Purpose of Inspection

- To assess compliance with pharmacy / medicines legislation & guidance of the PSI

- To provide assurance to the public that arrangements are in place to ensure patient safety

- To promote good, safe pharmacy practise and continuously improve standards.

Activity Types

- Registration related inspections (S.19 Act)

- Routine Inspections (S.67 Act)

- Investigations (S.67 Act)

- Mystery customers - Information

Inspection Process

Visit → Report → Response → Close → Visit (cyclical process)
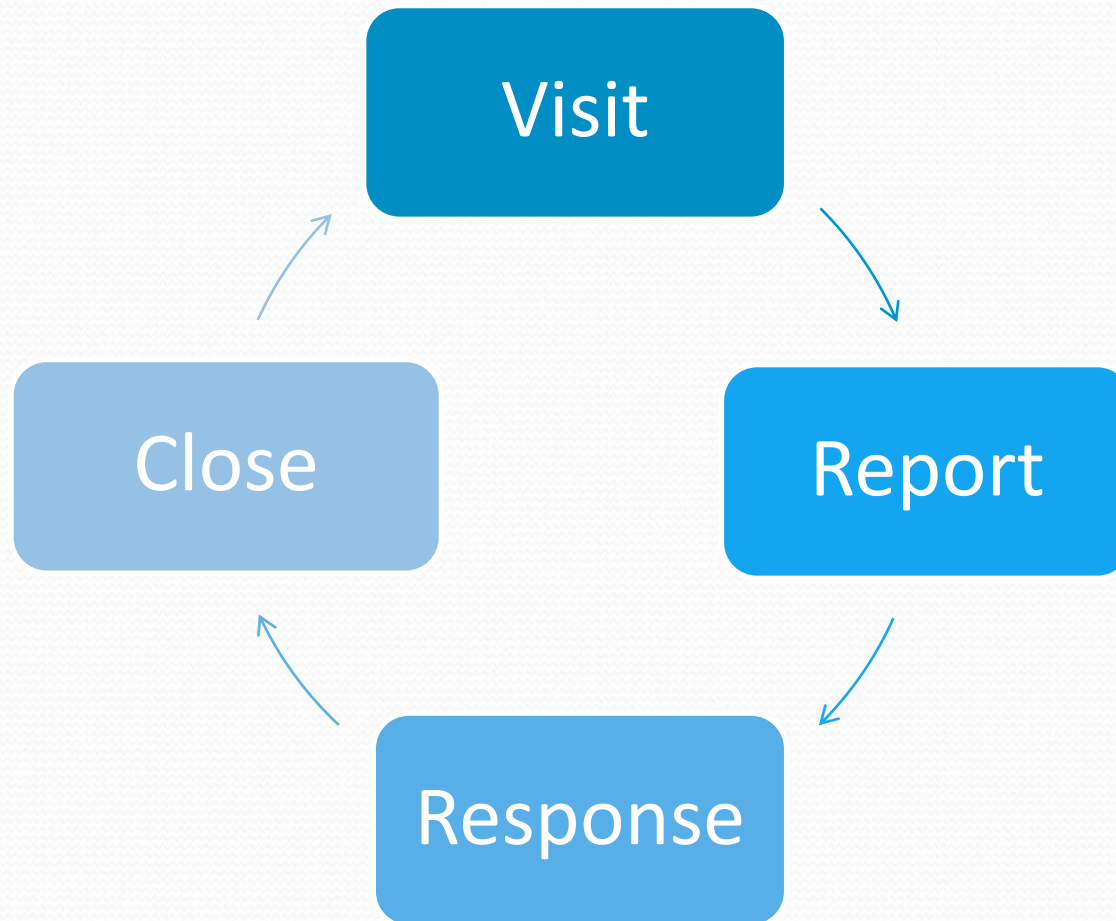
Visit – Routine Inspection

- Not notified
- Inspector - ID card and warrant
- Patients your priority

- Documents - Registers/SOPs/Prescriptions
- Premises - Dispensary/Storerooms/Bathrooms
- Feedback
- Takes c. 2 hours

The Report and Response

- **Report**
  - Superintendent Pharmacist
  - Observations - Compliance & Non-compliance
  - Required Actions - Confirmations
  - Cover Letter

- **Response**
  - Confirmations for each required action
  - Photographs

Consider Report

Regular Report

- Required actions in order
- Close report

Exceptions - (S.71)

- No action

- Complaint

- Take such other action as is considered appropriate:
    - Prosecutions/Undertakings/Meeting w/ Registrar/Referral

Investigation

When does PSI conduct investigation?
- Concern/Information - member public/agency
- Inspection or Mystery shopper activity

What do we look at?
- Dispensing Errors/Management Controlled Drugs/Veterinary medicine/Supply High Tech Medicines etc.

What happens after?
- Visit: Documents – Statements
- Report
- Considered by Registrar - (S.71 Act)

Statistics

2013	Total
Systems Inspection	388
Complaints	1
Prosecutions	0

Statistics

2014	Total
Systems Inspection	527
Complaints	1
Prosecutions	0

Statistics

Investigations	Total
2013	27
Complaints	6
Prosecutions	0
2014	13
Complaints	0
Prosecutions	0

Next Steps

Cycle 1 Inspections - End

Inspection Policy Project 2014

- Expert Group
- Survey on current PSI Inspection Policy
- Review of International/National practices
- Report & Recommendations
- New Inspection Policy - End of 2014.

Recurrent Issues at Inspection
and
How to Prepare

Recurrent Issues at Inspection

1) Premises and Storage Conditions

2) Quality Management Systems

3) Dispensing Practices

4) Emergency Supply of Medicines

5) Management of 'High Tech' Scheme

6) Management of Controlled Drugs

7) Residential Care Centres

8) Delivery

9) Management of Veterinary Medicines

Premises and Storage Conditions

☑ Premises
- ☑ Public Pharmacy Area
- ☑ Dispensary
- ☑ Patient Consultation Area
- ☑ Storage Areas

☑ Storage Conditions
- ☑ Temperature Monitoring
- ☑ Pharmaceutical Grade Fridge

Quality Management Systems

☑ Standard Operating Procedures

  ☑ Specific to Pharmacy

  ☑ Staff Training Records

  ☑ Records of Reviews

☑ Error / Incident Records

  ☑ Record

  ☑ Review

  ☑ Corrective Actions

Dispensing Practices

☑ Review of required Pharmacy Records

　　☑ Prescription Register (Daily Audit Report)

　　☑ Controlled Drugs Register

　　☑ Duty Register

☑ Prescriptions Requested for review, including:

　　☑ Controlled Drugs

　　☑ 'High Tech'

　　☑ Emergency Supply

Emergency Supply of Medicines

☑ At the request of Patient:

    ☑ Pharmacist must interview patient

    ☑ No more than 5 days supply, with exceptions

    ☑ Record as Emergency Supply, including reason

☑ At the request of Prescriber:

    ☑ Prescriber undertakes to provide the prescription within 72 hours

☑ No Schedule 2, 3 or 4 Controlled Drugs

    ☑ Exception: Phenobarbitone, Methylphenobarbitone supplied for the treatment of Epilepsy

Management of 'High Tech' Scheme

☑ Prescriptions
- ☑ 'High Tech' Prescription
- ☑ GP Prescription

☑ Patient Counselling

☑ Review of Therapy

☑ Documented Procedures
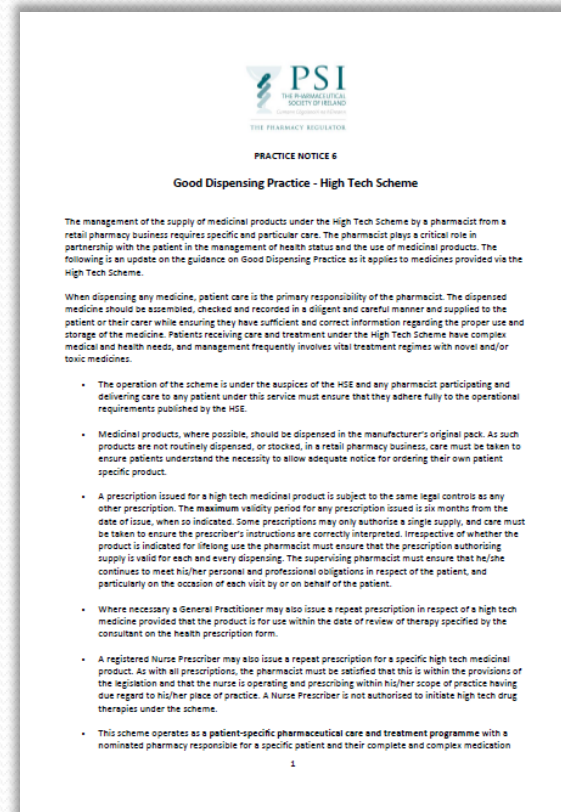
Management of Controlled Drugs

☑ Controlled Drugs Register

   ☑ Record all transactions

   ☑ Routine Balance Checks

☑ Prescriptions

   ☑ Specific Requirements

☑ Storage

☑ Witnessed Destruction
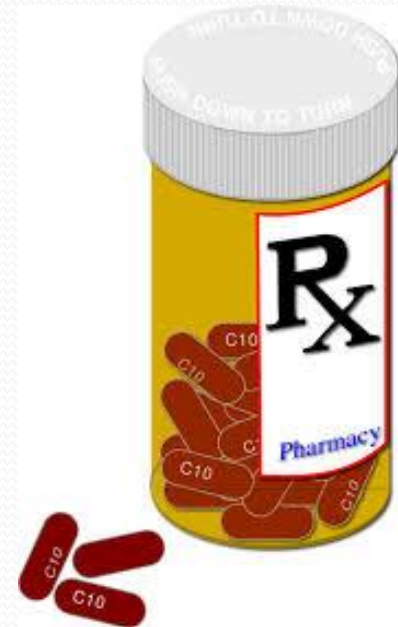
Residential Care Centres

☑ Use of Original Prescriptions

☑ Documented Procedures

  ☑ Specific to individual pharmacy

☑ Records

  ☑ Delivery

  ☑ Patient Counselling

  ☑ Medicines Use Reviews

Delivery

☑ PSI Guidance Document published July 2014

☑ Compliance with guidance will be looked at during future inspections

☑ What will be looked at?

   ☑ Appropriateness of Supply

   ☑ Method of Delivery

   ☑ Records of Delivery

   ☑ Policies and Procedures

Management of Veterinary Medicines

- ☑ Routes of Supply
- ☑ Record Keeping
    - ☑ Animal Remedies Register / Veterinary Register
    - ☑ Maintain for 5 years
- ☑ Prescriptions
    - ☑ Endorsing
    - ☑ Emergency Supply
- ☑ Storage of Veterinary Medicines
    - ☑ Pharmaceutical Grade Fridge

How to prepare for inspection?

☑ Self-Audit: Review the operation of your pharmacy

☑ Inspection Checklist

☑ Short guide to inspections

☑ Podcasts

☑ PSI Newsletters: Inspectors Advice

Useful Resources
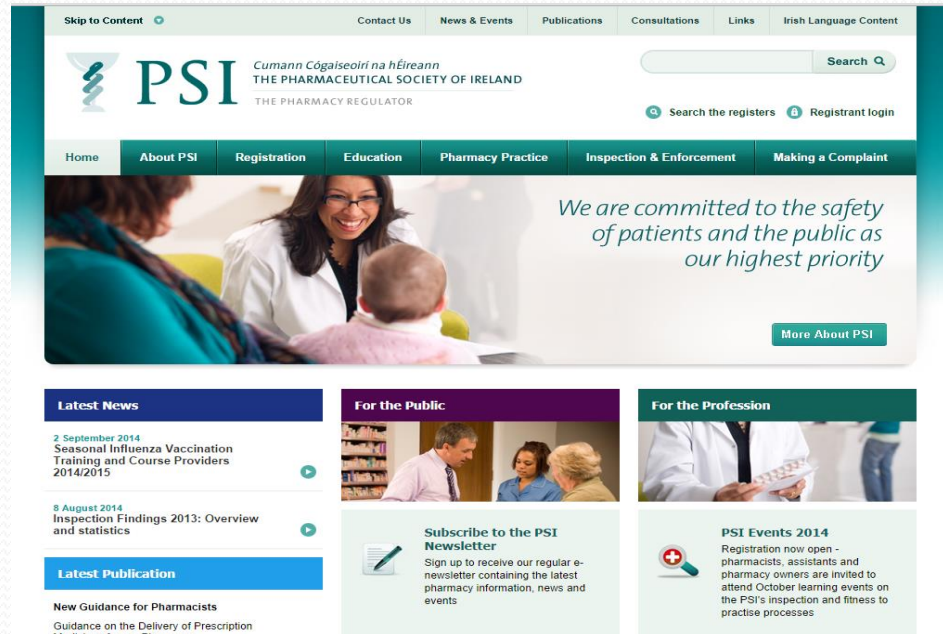
- www.thePSI.ie
- info@thePSI.ie
- Email Query Service
- PSI Newsletter

- Pharmacy Practice Guidance
- Inspection Checklists & Advice
- Making a Complaint/FTP Process Guides