PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Report of the Project Expert Group

on

A Strategic Review of the Current Policy for Routine Pharmacy Inspections

10 October 2014

Table of Contents

List of Appendices

1. Terms of Reference
2. Summary of Experience of Members of the Expert Group
3. Inspection and Enforcement Policy Document
4. PSI Checklist for Regular/Systems Inspections
5. Findings from 2013 Regular/Systems Inspections
6. Survey 1 and Survey 2 issued to all pharmacists, pharmacy owners and pharmaceutical assistants
7. Analysis of Survey 1 and Survey 2
8. Questionnaire issued to all PSI Authorised Officers involved in conducting Regular/Systems Inspections
9. List of key national stakeholders contacted
10. Letter issued to key national stakeholders
11. List of national and international organisations contacted
12. List of national and international organisations that responded
13. Questionnaire issued to list of national and international organisations
14. Summary of responses received from national and international organisations
15. Indicative structure for a pharmacy self-audit proposed by the Expert Group
16. Summary of the responsibilities and activities for the main players in the proposed model

EXECUTIVE SUMMARY

Overview of the Strategic Review of the Current Policy for Routine Pharmacy Inspections

Having regard to the fact the Pharmaceutical Society of Ireland (PSI) will have conducted an inspection in every community retail pharmacy in the State by the end of 2014, the Council of the PSI appointed an independent Project Expert Group on 26 June 2014 to review the current inspection policy and to advise on developing a new policy for routine PSI pharmacy inspections in accordance with its approved Terms of Reference.

The Expert Group met on 6 occasions over the course of the project.

The following research activities were undertaken to assist the Group in conducting its review:

- A detailed questionnaire was prepared and issued to approximately 60 national and international pharmacy and non-pharmacy regulatory and inspection bodies.
- A survey was issued to all registered Pharmacists, Pharmacy Owners and Pharmaceutical Assistants inviting feedback on the current PSI Inspection Policy.
- Views from key national stakeholders namely Department of Health, Health Service Executive, Pharmacy and Pharmacist Representative Bodies and Patient Representative Bodies were invited on the current PSI pharmacy inspection policy.
- A questionnaire was issued to all PSI Authorised Officers currently engaged in conducting routine pharmacy inspections.

In conducting its review, the Group analysed the findings from its research and drew on the collective expertise in the areas of regulation, inspection and pharmacy practice to prepare this report of its review of routine pharmacy inspections comprising the following sections:

- Review of the pharmacy landscape in Ireland in 2014
- Analysis of the current PSI inspection policy
- Analysis of research conducted into national and international regulatory policy
- Findings and recommendations.

Overview of the pharmacy landscape in Ireland in 2014

Patient safety is central to the ethos of the legislative framework for medicines and pharmacy in Ireland. The commencement and implementation of the Pharmacy Act 2007 marked a new era for the regulation of pharmacy and pharmacists in Ireland by establishing the PSI as the statutory regulator of pharmacy. In addition, a number of statutory Rules and Regulations made under the Act set out in greater detail the procedures and requirements which are operated by the PSI in carrying out its various functions under the provisions of the Act.

The Pharmacy Act and the Rules and Regulations made under it, together with a number of further pieces of medicines, veterinary, controlled drugs and poisons legislation, provides for a robust legislative framework, the overall purpose of which is to ensure that every practice, procedure and process that occurs from manufacture of the medicine to the administration of a medicine by a patient is safe.

Overview of Current PSI Inspection Policy

Section 7 of the Pharmacy Act 2007 places an overarching obligation on the PSI to supervise compliance with the Act and the Rules and Regulations made under it. The Act provides for general powers of inspection and investigation under Section 67 and specific authority to conduct an inspection as part of the process for the registration of a retail pharmacy business under Section 19.

In accordance with the current PSI Inspection and Enforcement Policy, the objectives of the PSI inspection function are to promote good and safe pharmacy practice within retail pharmacy businesses. In addition, the PSI aims to improve the delivery of pharmacy services and the standard of operation of these entities. It also aspires to promote and ensure high standards of voluntary compliance with legislative requirements, PSI guidelines, best practice requirements and the PSI Code of Conduct for Pharmacists.

Since its establishment in 2007, in accordance with the legislation and current policy provisions, the Inspection and Enforcement Unit of the PSI has been conducting three main types of inspections:

- Registration inspections (under the authority of Section 19 of the Pharmacy Act 2007)
- Regular/Systems inspections (under the authority of Section 67 of the Pharmacy Act 2007)
- Investigations (under the authority of Section 67 of the Pharmacy Act 2007)

The scope of this strategic review was limited to the Regular/Systems inspections conducted under Section 67 of the Pharmacy Act.

Findings and Recommendations

The Group considered the advantages and limitations associated with the current Regular/Systems inspection model. In doing so, the Group was cognisant that any proposal for a future inspection type would have to be compatible with the overall regulatory framework for the practice of pharmacy in Ireland set out in the Pharmacy Act and provide the appropriate assurance to the PSI that the pharmacy inspected was providing a safe and effective pharmacy service to patients and the public. It also acknowledged that the future model would have to be sufficiently agile to keep pace with future pharmacy developments. Therefore the Group recommended that the PSI should adopt a new type of routine pharmacy inspection which addresses the limitations identified with the current Regular/Systems Inspection.

The Group agreed that self-assessment by the Supervising Pharmacist would be a very important element in providing assurance of the ongoing internal review of the systems and risks in place in the pharmacy. It would also facilitate a culture of continuous improvement of pharmacy practice and ensure that the pharmacy is operating to the highest standards of patient safety at all times. The Group was of the view that a self-assessment which provides for a detailed reflection and analysis of the manner in which the pharmacy conducts its activities and complies with all relevant pharmacy and medicines legislation would be necessary. It also considered that the self-assessment should provide for the review of all of the practices and assessment of the potential risks at the pharmacy. The Group also agreed that the term self-audit was more appropriate to describe this type of exercise.

The Group then considered how such a process of self-audit could be linked to the inspection process to provide the necessary assurances to the PSI regarding patient safety at the pharmacy. Hence, the Group proposed a model for future inspections which is based on the PSI Authorised Officer (Inspector) conducting a review of the self-audits at the pharmacy together with a review of other documentation and records, examination of the premises, observation of the practices at the pharmacy and engaging with the staff at the pharmacy.

The Group also recognised the differences in the practice environment and patient needs in a hospital pharmacy which is registered as a retail pharmacy business compared to a community pharmacy practice. However, it also recognised that there are a number of the provisions relating to the obligations on the pharmacy, the pharmacy owner and the pharmacist in the legislation as well as in the PSI guidance and PSI Code of Conduct for Pharmacists which were equally relevant to both practice settings and therefore hospital pharmacies which are registered as Retail Pharmacy Businesses should also be subject to routine PSI inspections.

Taking all of this into consideration and in light of the approach, scope and content for the future model for a routine inspection proposed, the Group agreed that this type of inspection should be called a "Pharmacy Governance and Practice Inspection".

The Group noted the following significant advantages make that the Pharmacy Governance and Practice Inspection suitable and appropriate for the PSI:

- It provides for a mandatory process of ongoing internal review of the systems and risks in place in the pharmacy and facilitate a culture of continuous improvement of pharmacy practice and ensures that the pharmacy is operating to the highest standards of patient safety at all times.
- It facilitates the Inspector in gaining insight in to the governance structures in the pharmacy and verifying that the pharmacy is operating in compliance with the legislation and PSI guidance.
- Pharmacists and pharmacies would be encouraged to proactively demonstrate the positive practices and innovations in place at the pharmacy during the inspection including in line with the Department of Health vision set out in Future Health: A Strategic Framework for Reform of the Health Service 2012-2015.
- It facilitates the expansion of the scope of future inspections to address future developments in pharmacy practice.
- It facilitates the utilisation of a number of different methods during the inspection including observation, documentary review, examination of premises and questioning of other staff members to verify that the practices at the pharmacy are appropriately safe.
- By providing notification in advance of the inspection, the Supervising Pharmacist will be present to engage with the inspector and to optimise inspection outcomes.
- The proposed model will facilitate the routine inspection of all registered retail pharmacy businesses operating in both community and hospital settings in the State.

The Group also noted the following potential challenges:

- The model will represent a significant change from current policy which is based on unannounced inspections and will require an investment of time and resources by the PSI to implement successfully.

- Superintendent, Supervising Pharmacists and pharmacy owners will have to adjust to a new type of routine inspection which the PSI will have to support though engagement and guidance.
- The PSI will have to design, pilot and implement a completely new type of inspection. Furthermore, having regard to the fact that to date hospital pharmacies have only been inspected as part of a registration process, it will be necessary to develop specific inspection processes and guidance to support and facilitate routine inspections of hospital pharmacies in the future.
- It will be necessary for the Pharmacy Owner and the Superintendent Pharmacist to support the Supervising Pharmacist in completing the self-audit. It will take time for the Supervising Pharmacist to complete the type of self-audit which may be perceived as an additional administrative burden on the pharmacy.

Overall, the Group was of the view that the Pharmacy Governance and Practice Inspection would provide for a very robust, risk-based and flexible model of inspection. It would also provide substantial assurances to the PSI that the Supervising Pharmacist is effectively discharging his/her function at the pharmacy on an ongoing basis in the interest of patient safety. The Group was also of the view that this model would ultimately result in improved standards of practice in pharmacies.

Finally, the Group noted that unannounced activities also have a very important role in the PSI's regulatory toolkit in assuring patient safety. The Group was of the view that the introduction of the Pharmacy Governance and Practice Inspection does not limit future unannounced inspection or investigation activities which may be necessarily conducted by the PSI under the authority of Section 67 of the Pharmacy Act.

Implementation of the Pharmacy Governance and Practice Inspection

Recognising that Pharmacy Governance and Practice Inspection includes some significant changes from the current policy for routine pharmacy inspections, the Group was of the view that the success of introducing this inspection type would be highly dependent on the successful engagement and communication by the PSI with pharmacists and pharmacy owners over the course of the implementation of the new model.

The Group concluded that a two-stage process should be adopted for implementation to allow time for both the PSI to develop its processes and for the profession to become accustomed to the new model of inspection. Finally, the Group was of the view that the PSI should carefully monitor the roll out of the new model and provide a mechanism for inspectors and pharmacists to feedback to ensure maximum opportunity for sharing of information and learning from the new processes.

RECOMMENDATIONS OF THE EXPERT GROUP

Recommendation 1

The Group recommends that the PSI should adopt a new type of routine pharmacy inspection which addresses the limitations identified with the current Regular/Systems Inspection.

Recommendation 2

The Group recommends that the PSI should implement a system whereby pharmacists conduct regular detailed reviews of the practices and potential risks at the pharmacy to facilitate and encourage a culture of continuous improvement of pharmacy practice and ensure that the pharmacy is operating to the highest standards of patient safety at all times.

Recommendation 3

a) The Group recommends that the PSI develops a template to facilitate a detailed reflection and analysis of the manner in which the pharmacy complies with all relevant pharmacy and medicines legislation and should provide for the review of all of the practices and assessment of the potential risks at the pharmacy. This should be called the PSI Self-Audit.

b) The Group also recommends that it should be mandatory for all Supervising Pharmacists to compete self-audits of the pharmacy for which they are responsible at least biannually (every six months).

c) Furthermore, the Group recommends that Superintendent Pharmacists and Pharmacy Owners should be obliged to confirm to the PSI that such self-audits are being completed in this way.

Recommendation 4

a) The Group recommends that a type of pharmacy inspection should be introduced which would also be conducted under Section 67 of the Pharmacy Act. The inspection should be based on the PSI inspector meeting with the Supervising Pharmacist at the start of the inspection and conducting a review of the self-audits which have been completed by the Supervising Pharmacist for the pharmacy. Through a combination of documentation review, examination of the premises, observation of the practices at the pharmacy, and asking questions the Inspector will establish that the pharmacy is operating in compliance with the legislation, PSI guidance and is providing a safe service to patients and the public by establishing the governance structure in the pharmacy, the manner in which all aspects of the pharmacy are operated and the manner in which risks are identified and managed in the pharmacy.

b) The Group recommends that this type of inspection should be called a “Pharmacy Governance and Practice Inspection”.

c) The Group also recommends that the scope/content of a Pharmacy Governance and Practice Inspection should be appropriately flexible to ensure that the inspection process keeps pace with the expected continued evolution of the role of pharmacists and pharmacies in the Irish health system.

Recommendation 5

The Group recommends that hospital pharmacies which are registered as Retail Pharmacy Businesses should also be subject to routine PSI inspections.

Recommendation 6

a) The Group recommends that the PSI should continue to issue a written report after each "Pharmacy Governance and Practice Inspection" to provide feedback on the findings from the inspection.

b) The Group also recommends that the PSI develops a process to extract key findings recorded in these reports for the purposes of publishing aggregate findings and relevant statistics on the PSI website, Annual Report etc. in the interests of transparency and learning.

Recommendation 7

a) The Group recommends that the Pharmacy Governance and Practice Inspection should be conducted by the PSI at sufficiently regular intervals to provide the necessary assurances regarding each registered retail pharmacy business. The PSI should prioritise Pharmacy Governance and Practice Inspections on the basis of a risk assessment of the information available to it.

b) The Group recommends that the PSI should also continue to schedule Pharmacy Governance and Practice Inspections of pharmacies with similar risk profiles on the basis of their geographical location (i.e. pharmacies in a particular region/along a particular route would be scheduled for inspection together) to maximise the efficient use of inspector time and resources.

Recommendation 8

The Group recommends that the PSI should develop an implementation strategy to manage the challenges identified with the Pharmacy Governance and Practice Inspection.

Recommendation 9

The Group recommends that the implementation strategy for the Pharmacy Governance and Practice Inspection should take place in two stages:

- Stage 1: Design and Piloting
- Stage 2: Full Roll-out – to be commenced as soon as possible after Stage 1

Recommendation 10

The Group recommends that Stage 1 include at least the following:

- Introduce the Pharmacy Governance and Practice Inspection to each of the key groups of personnel (Superintendent Pharmacists, Supervising Pharmacists, employee pharmacists, pharmacy owners, Pharmaceutical Assistants, various pharmacy and representative bodies etc.) as soon as possible utilising a combination of different methods of communication and engagement including local and regional meetings, videos, podcasts, website updates, information documents etc.
- Design new inspection processes for piloting.
- Select the pharmacies to receive pilot inspections.
- Prepare guidance to support the proposed model including how to complete the self-audit and how to prepare for a new-type inspection.
- Train Inspectors in conducting the pilot inspections.
- Conduct a sufficient number of pilot inspections to elicit feedback to refine and further develop new inspection processes based on the proposed model (including reporting processes) and guidance based on the proposed model.
- Develop a framework to facilitate judgement by the Inspector during the inspection process.

Recommendation 11

a) The Group recommends that high quality communication and engagement to each of the key groups of personnel (Superintendent Pharmacists, Supervising Pharmacists, employee pharmacists, pharmacy owners, Pharmaceutical Assistants, various pharmacy and representative bodies) would be very important in achieving successful implementation of the Pharmacy Governance and Practice Inspection in Stage 2.

b) The Group recommends that a combination of different methods of engagement including local and regional meetings, videos, podcasts, website updates, information documents etc. should be employed by the PSI to ensure that pharmacists and pharmacy owners are afforded a full and fair opportunity to become informed of and comply with the expectation of the PSI in relation to the operation of the pharmacies for which they are responsible under the proposed model of inspection. In addition to this, it recommended the issuance of a complete set of clear, unambiguous and up-to-date guidance on legislative and best practice requirements for pharmacy in Ireland which would be reviewed and updated as necessary over the course of the roll out stage.

c) The Group also recommends that the PSI carefully monitors the roll out of Pharmacy Governance and Practice Inspection and provides a mechanism for inspectors and pharmacists to feedback to ensure maximum opportunity for sharing of information and learning from the new processes.

Recommendation 12

The Group recommends that two separate, but parallel approaches to the roll out of Pharmacy Governance and Practice Inspections for both community and hospital practice settings.

Recommendation 13

The Group recommends that it would be a reasonable target for the PSI to conduct a Pharmacy Governance and Practice Inspection in every pharmacy in the State under the proposed model within 5 years of the commencement of the full roll-out (i.e. Stage 2) subject to certain factors such as the availability of PSI resources generally (specifically inspector resources).

Recommendation 14

The Group recommends that the PSI continues to conduct its other activities under Section 67 of the Pharmacy Act 2007 on an unannounced basis as such visits provide for a more accurate assessment and insight into the operation of a pharmacy and its compliance with pharmacy and medicines legislation on a day-to-day basis as experienced by patients.

1 INTRODUCTION

Having regard to the fact that the Pharmaceutical Society of Ireland (PSI) will have completed the first cycle of pharmacy inspections by the end of 2014, the Council of the PSI made a decision in February 2014 to commence a strategic review of the current policy on the routine inspection of pharmacies to form the basis for the policy for the next cycle of routine inspections. The Council also decided to appoint a team of national experts to assist with the review.

Terms of Reference for the review were prepared and endorsed by the Council of the PSI. A copy of the Terms of Reference is included in Appendix 1

An independent Project Expert Group was appointed by the Council of the PSI on 26 June 2014 to review the current inspection policy and to advise on developing a new inspection policy for the PSI in accordance with the approved Terms of Reference:

- Noel Conroy – former Garda Commissioner (Chairperson)
  Person with experience of regulation or enforcement
- Kevin O'Donnell – Market Compliance Manager, Health Products Regulatory Authority (HPRA)
  Person with expertise in risk management
- Niall Byrne – Deputy Director of Regulation, Health Information and Quality Authority (HIQA)
  Person with experience in inspection (other than pharmacy inspection)
- Caroline McGrath, MPSI – Clinical Governance Pharmacist, Boots Ireland
  Community pharmacist
- Michael Tierney, MPSI - Superintendent, Supervising Pharmacist at Tierney's Pharmacy, Rathdrum, Co Wicklow
  Community pharmacist
- Veronica Treacy, MPSI - Director of Pharmacy, St James' Hospital, Dublin
  Hospital pharmacist – Superintendent Pharmacist
- Marese Damery – Health Check Coordinator, Irish Heart Foundation
  Representative of public/patient interest

The Expert Group was supported by the Inspection and Enforcement Unit of the PSI and Lucia Crimin was assigned the role of Project Manager for the project.

Appendix 2 includes a short summary of the experience and expertise of each member of the Expert Group.

The Terms of Reference set out the objectives of the Expert Group as follows:

- Define the rationale and purpose of the routine pharmacy inspection;
- Examine current PSI inspection policy;
- Conduct research into national and international inspection models in healthcare and other relevant sectors;
- Consult with key national stakeholders;
- Prepare a report based on the findings containing a recommendation for a new inspection policy and a new inspection model for implementation by the PSI.

The work of the project commenced in early July and the Expert Group met on 5 further occasions[1].

The following research activities were undertaken to inform the work of the project:

- Research into national and international regulatory and inspection policy. A detailed questionnaire was prepared and issued to approximately 60 national and international pharmacy and non-pharmacy regulatory bodies.
- Feedback of Pharmacists, Pharmacy Owners and Pharmaceutical Assistants on the current PSI Inspection Policy for routine inspections. Two surveys were prepared on the current PSI inspection process – one for those who have experienced a PSI inspection and a second for those who have not experienced a PSI inspection or are not likely to be inspected (by virtue of their area of practice). Electronic versions of the two surveys were issued on Friday 25 July by email to all registered pharmacists, pharmacy owners and pharmaceutical assistants. Hard copy versions of the two surveys on current PSI inspection processes were issued on 30 July to those pharmacists, pharmacy owners and pharmaceutical assistants who, according to the PSI Register, do not have an email address. The survey closed on Monday 11 August.
- Views of key national stakeholders namely the Department of Health, HSE, Pharmacy and Pharmacist Representative Bodies and Patient Representative Bodies on the current PSI pharmacy inspection policy.
- Feedback from Authorised Officers of the PSI on the current PSI Inspection Policy for routine inspections. A questionnaire was prepared and issued to 7 Authorised Officers currently involved in the inspection process.

The Expert Group analysed the findings of this research and drew on their collective expertise in the areas of regulation, inspection and pharmacy practice to prepare a report of its review of routine pharmacy inspections comprising the following sections:

- Review of the pharmacy landscape in Ireland in 2014
- Analysis of the current PSI inspection policy
- Analysis of national and international regulatory practice
- Findings and recommendations.

In accordance with the approved Terms of Reference, this report will be submitted to the Registrar of the PSI and to the Chairperson of the Inspection and Enforcement Committee of the PSI for their consideration. The Chairperson of the Committee will then issue the report together with the comments from the Registrar and its recommendation to the Council of the PSI for decision.

[1] The Expert Group met on the following dates: 8, 15, 25 July, 22 August, 12 September, 6 October 2014.

2 REVIEW OF PHARMACY LANDSCAPE IN IRELAND IN 2014

Currently in Ireland there are over 5,200 registered pharmacists, comprising 64% community-based pharmacists and 10% hospital-based pharmacists. The remaining registered pharmacists are employed in the pharmaceutical industry, in regulation or in the educational sector.

The majority of pharmacists practice their profession in either a community or hospital setting. The Pharmacy Act 2007 defines a retail pharmacy business as being *"A business (not being a professional practice carried on by a registered medical practitioner or a registered dentist) which consists of or includes the sale or supply of medicinal products other than medicinal products on a general sales list (whether or not such products on such a list are also sold or supplied in the course of the business)".*

There are over 1,830 registered retail pharmacy businesses currently in operation in Ireland: approximately 1,760 community based retail pharmacy businesses and 70 hospital based retail pharmacy businesses.

2.1 The Role of the Pharmacist in the Irish Healthcare System

Pharmacists working in community and hospital practice settings are responsible for controlling, dispensing and distributing medicines and providing pharmaceutical care. Activities undertaken by pharmacists on a daily basis in the course of their practise include:

- reviewing prescriptions, review of therapy prior to dispensing and finally dispensing of prescription medicines in accordance with the prescription.
- supervising the medicines supply chain and ensuring that pharmacy premises and systems are fit for purpose and work to legal and ethical guidelines to ensure the correct and safe supply of medical products to the general public.
- supplying non-prescription medicines and medical devices and instruct patients on the appropriate use of such items.
- providing services such as the administration of the Seasonal Influenza Vaccine.
- maintaining and improving public health by providing advice and information on medicines and lifestyle choices to maximise health and wellbeing including smoking cessation, weight management etc.
- advising other healthcare professionals about safe and effective medicines use, and safe and secure supply of medicines.

Pharmacists working in a hospital setting may also attend ward rounds and are involved in selecting treatments for patients as part of the patient's multi-disciplinary care team. Advanced and specialist roles are now more common in the area of hospital pharmacy, e.g. palliative-care, oncology, intensive care and antimicrobial stewardship pharmacists.

As frontline services, it is essential that the practice of pharmacy by all pharmacists in all practice settings and the operation of pharmacies are compliant with medicines and pharmacy law to ensure patients and the public are appropriately protected.

2.2 Regulation of Pharmacists and Pharmacies in Ireland

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body which regulates the professional practice of approximately 5,200 pharmacists, 450 pharmaceutical assistants and 1,830 pharmacies in Ireland. It was established by the Pharmacy Act 2007 and its roles and functions are also defined in this Act. The primary role of the PSI is to protect the public interest through the effective regulation of the profession and practice of pharmacy. The PSI is accountable to and must report to, the Minister for Health, the Department of Health, and to the Oireachtas.

The PSI is governed by a 21 member Council, with a non-pharmacist majority, appointed by the Minister for Health, which performs the functions of the PSI in accordance with the Act. The Council may delegate any of its functions to any of the six Advisory Committees or to the Registrar or to any other employee of the PSI. The PSI operates as the Pharmacy Regulator in accordance with a defined mission, vision and set of values, approved by the Council of the PSI and which collectively shape its commitment to the safety of patients and the public, as its highest priority.

An executive staff at the PSI offices in Dublin supports the work of the Council. The main operating units include professional development and learning, registration and qualification recognition, pharmacy practice development and inspection and enforcement. The PSI is also required to maintain a fitness to practise and legal affairs unit for the purposes of Part 6 of the Act which deals with complaints, enquiries and discipline.

2.3 Legislative Framework for Pharmacy Practice in Ireland

Patient safety is central to the ethos of the legislative framework for medicines and pharmacy in Ireland. Each piece of legislation regulates a different aspect of the medicine production and supply chain, to ensure the process is highly governed, to try to mitigate poor practice and poor standards in order to prevent patient harm. There are many different types of medicinal product that can be supplied in the pharmacy and the legislation is designed to set out the conditions for the supply of these different medicines. The pieces of legislation that govern pharmacy practice include:

- Pharmacy Act 2007
- Regulation of Retail Pharmacy Businesses Regulations 2008
- Irish Medicines Board Act 1995 and 2006 and the regulations made thereunder
- Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended
- Misuse of Drugs Acts 1977 and 1984 and Misuse of Drugs Regulations 1988 as amended
- Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998
- Health (Pricing and Supply of Medical Goods) Act 2013.
- European Communities (Animal Remedies) No 2 Regulations 2007
- Poisons Act 1961 and 1977 and Poisons Regulations 2008

The following sections will outline how each piece of legislation applies to the day-to-day practice of pharmacy.

2.3.1 Pharmacy Act 2007

The Pharmacy Act 2007 together with the regulations made under it, statutory rules and a new code of conduct for pharmacists provides for a regulatory framework for pharmacy in Ireland.

One of the main outcomes of the Pharmacy Act 2007 was the establishment of the PSI, which regulates pharmacists and pharmacies in Ireland. There are a number of statutory rules which set out in greater detail the procedures and requirements which are operated by the PSI in carrying out its various functions under the provisions of the Act. These relate to the registration of pharmacists, retail pharmacy businesses and pharmaceutical assistants, the working of Council, pharmacy education and training, and fees. The Act also created two important roles in the overall management and clinical governance at the pharmacy. In addition the Act provides for processes for fitness to practice, accreditation of pharmacist education, continuing professional development, complaints against pharmacists and pharmacies, inspection and enforcement, practice guidelines, public and patient information and a provision for a statutory code of conduct for pharmacists.

Pharmacists and pharmaceutical assistants must be registered in the registers kept by the PSI in order to practise. In addition, in order to open and operate, a pharmacy must be registered as a retail pharmacy business in the register kept by the PSI. Under the new system of registration provided for in Part 4 of the Pharmacy Act 2007, registered pharmacists, pharmaceutical assistants and pharmacy owners are required to apply for continued registration on an annual basis. Each registrant receives an annual certificate of registration, which must be clearly displayed in the public domain of the pharmacy.

The Act also provides for two particular pharmacist roles in the overall management and clinical governance of the pharmacy: the Superintendent Pharmacist and Supervising Pharmacist. The Superintendent Pharmacist is a registered pharmacist with at least three years' experience and is in control of the management and administration of the sale and supply of human and veterinary medicines and must be carried out in accordance with all legal requirements. In addition, each pharmacy must have a Supervising Pharmacist who is in whole time charge of the pharmacy. This pharmacist must also have at least three years' experience. It is possible that both roles can be discharged by the same person.

Collectively Sections 7, 67 and 71 of the Pharmacy Act 2007 give the PSI significant powers of inspection, investigation and enforcement. The PSI inspects retail pharmacy businesses (pharmacies) to assess compliance with the Act and with other pharmacy and medicines legislation, in the interests of patient safety and public protection. Inspections and investigations are carried out by Authorised Officers of the PSI. The PSI carries out two main types of inspections - inspections of new pharmacy openings under Section 19 and routine compliance inspections under Section 67 of the Act. The PSI also conducts investigations which typically involve an inspection or series of inspections, as well as speaking with the pharmacy owner, pharmacist or other staff of a pharmacy, and review and seizure of records or other items, as part of the investigation process. The Act creates certain offences relating to pharmacy which the PSI may prosecute through the courts. A full review of the current PSI inspection policy is included in Section 4 of this report.

A statutory Code of Conduct was introduced under the Act and was formally laid before the Houses of the Oireachtas in February 2009. It sets out the key principles or professional ethical standards in accordance with which pharmacists should practice their profession. Every pharmacist has an

obligation to comply in full with the statutory Code of Conduct. Superintendent and Supervising pharmacists have an important role in ensuring and supporting compliance.

The Pharmacy Act provided for a system whereby complaints can be made by, or on behalf of, any person to the PSI about a pharmacist or pharmacy. This includes patients, members of the public, employers and other health professionals. The Registrar of the PSI may also make a complaint about a pharmacist or pharmacy. The Preliminary Proceedings Committee (PPC) will then consider the complaint and may request further information and/or documentation from the pharmacist or the retail pharmacy business. If the PPC advises Council that there is sufficient cause to warrant further action, then a decision will be made by the PPC to either refer the complaint to mediation or to a Committee of Inquiry. There are two Committees of Inquiry to which a complaint may be referred - the Professional Conduct Committee or the Health Committee. The choice of committee will depend on the nature of the complaint. Complaints which concern matters of professional misconduct or poor professional performance will normally be referred to the Professional Conduct Committee.

2.3.2 Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No 488 of 2008)

The Regulation of Retail Pharmacy Businesses Regulations 2008, made under Section 18 of the Act set out certain requirements to be complied with by persons carrying on a retail pharmacy business to ensure that the pharmacy is operated in a manner which is safe for patients and the public.

The following is a summary of the requirements set out in the Regulations:

- The sale or supply of all medicines in the pharmacy, including veterinary medicines and general sale medicines and the dispensing and compounding of prescriptions for human and veterinary medicines, must be carried out by or under the personal supervision of a registered pharmacist.
- Specific requirements in respect of the sourcing, sale, supply, disposal and keeping of records in respect of medicinal products for human and veterinary use.
- Requirements in respect of staff, premises, equipment and procedures are also set out including the requirement for a separate and dedicated patient consultation area within the public part of the pharmacy to ensure privacy and dignity for patients in their dealings with the pharmacist.
- Defined two key roles in the clinical governance of the pharmacy, namely the Supervising and Superintendent Pharmacists who are accountable for the proper conduct of the pharmacy for which they are responsible. The regulations specify the responsibilities that must be discharged by superintendent and supervising pharmacist as well as the pharmacy owners in relation to staff, premises, equipment and procedures to avoid the deterioration of any medicines stored, dispensed, compounded or sold.
- The Superintendent Pharmacist and Pharmacy Owner must be satisfied as to the identity and registration status of any pharmacist employed in the pharmacy. They must also ensure that all other staff working at the pharmacy have the knowledge, skills, training and general fitness to practise required to discharge the duties assigned to them.
- A new requirement was also introduced to maintain a contemporaneous duty register of the pharmacists on duty for every day that the pharmacy is open and operational to the public.
- Reinforce many of the obligations that apply to pharmacists under legislation governing for human and veterinary medicines, controlled drugs, animal remedies and poisons.
- Created a number of offences under the Pharmacy Act 2007.

The Regulations also put on a statutory footing many aspects of good pharmaceutical practice which did not previously have any legislative basis, relating to matters such as review of the prescription by the pharmacist in advance of supplying any of the medicines on it to the patient as well as providing the patient with all of the relevant information, advice and counselling for that medicine. There is a mirror provision in the Regulations which requires that the pharmacist provides appropriate advice and counselling to a patient prior to completion of the sale or supply of a non-prescription medicine. The Regulations also introduced a requirement to have documented procedures in place (Standard Operating Procedures – SOPs) at the pharmacy describing the main activities conducted at the pharmacy.

2.3.3 Irish Medicines Board Act 1995 & 2006

The Irish Medicines Board Act 1995 & 2006 established the Irish Medicines Board (IMB) as the competent authority for medicines in Ireland. The IMB replaced the National Drugs Advisory Board in 1995. More recently, in July 2014, arising from a provision in the Health (Pricing and Supply of Medical Goods) Act 2013, the IMB was renamed the Health Products Regulatory Authority (HPRA).

The Irish Medicines Board Act gave the IMB the power to grant product authorisations for human and animal medicines, enabling medicinal products to be put on the market. It also authorised the issuing of manufacturing and wholesaling licences. The Act also enabled the EU directive, 2001/83/EC which provides for an overarching framework for the regulation of human medicines at EU level, to be transposed into national law, thus resulting in the development of a range of regulations known as the Medicinal Products Regulations as follows:

- Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended
- Medicinal Products (Control of Advertising) Regulations 2007
- Medicinal Products (Control of Placing on the Market) Regulations 2007
- Medicinal Products (Control of Wholesale Distribution) Regulations 2007
- Medicinal Products (Control of Manufacture) Regulations 2007

Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended are one of the main pieces of legislation that relate to the practice of pharmacy on a day-to-day basis.

2.3.4 Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended

In recognition of the fact that medicines are not ordinary commercial items, the main objective of these regulations is to apply controls to the sale and supply of medicines, including the legal status of supply, the prescribing and prescription requirements and the conditions attached to supply, all intended to prevent patient harm and preserve patient safety as concerns the use of medicines.

There are three main reasons for restricting medicines to supply on prescription, or through retail pharmacy business, namely:

- To prevent an individual initiating self-treatment for more serious or prolonged conditions, therefore restricting their access to treatments which require professional healthcare and supervision.

- To protect the health of the public by restricting the availability of drugs with serious abuse potential or the ability to cause harmful side effects, also those products whose misuse could lead to the emergence of resistant microorganisms
- To ensure patient safety by determining that the pharmacist reviews the medicine therapy and counsels the patient appropriately.

In addition, these regulations facilitate the control of certain medicines as pharmacy-only medicines. The legal status for supply of a medicinal product is a condition of the marketing authorisation. The categories for supply of a medicine are:

- Subject to prescription:
  - Non-renewable: dispensed once by the pharmacist unless the doctor directs otherwise
  - Renewable: dispensed for up to six months by the pharmacist unless the doctor directs otherwise
- Not subject to prescription:
  - Pharmacy-only: available under the supervision of a pharmacist
  - General sale: can, with reasonable safety, be sold without the supervision of a pharmacist

The HPRA is responsible for deciding the legal supply category for a medicine. The supply category is specific to the product and is part of the marketing authorisation. The other facet of these regulations concerns prescribing, and prescription requirements, which indirectly control the supply of medicines to the patient in the following ways:

- Conditions on registered nurses and midwives who wish to prescribe. The regulations outline the conditions under which nurse prescribers can do so and the obligations they must fulfil.
- The regulations also outline the prescription writing requirements that must be adhered to in order to make the prescription legally valid so that the medicines can be dispensed. Exemptions from prescription requirements are described. They also outline specific dispensing practices for certain types of prescriptions including repeat prescriptions.
- There are provisions in the regulations to provide for emergency supply situations at the request of a patient or practitioner.
- The regulations also include details of the information that must be included on the label of dispensed medicines. They also include the information to be recorded in the prescription register, after a medicine has been dispensed. Exemptions from recording requirements are also outlined. Details of a register that must be maintained for mifepristone supply is also described.
- Conditions attached to the supply of paracetamol are outlined in the regulations.
- The regulations describe the medicines which are permitted and are not permitted to be supplied by mail order or sold in vending machines.

The regulations were amended in 2011 to enable the administration of the Seasonal Influenza Vaccine by pharmacists in community pharmacies.

2.3.5 Misuse of Drugs Acts

The Misuse of Drugs Acts 1977 and 1984 together with the regulations made thereunder have ensured Ireland's compliance with its obligations under international law to prevent the misuse of substances and to ensure that certain substances are available for use as medicines.

The Misuse of Drugs Act 1977 (as amended) provides for the regulation and control of the import, export, production, supply and possession of "controlled drugs". The effect of controlling a substance under the Act is to make it an offence to possess that substance. The Minister for Health is empowered to then make orders and regulations to permit different levels of legitimate control of substances based on the health risk, potential for misuse and validity of legitimate use.

The Misuse of Drugs Act 1984 made several amendments to the 1977 Act and set out various procedural matters in relation to prosecution, penalties and offences. It also prohibited the printing, sale and distribution of publications containing any material or advertisements which advocate or encourage the illegal use of controlled drugs. The 1977 Act was further updated by the Irish Medicines Board (Miscellaneous Provisions) Act 2006 to set out the conditions under which registered nurses can prescribe certain controlled drugs and the specific requirements that they must adhere to.

2.3.6 Misuse of Drugs Regulations 1988 (as amended)

The Misuse of Drugs Regulations 1988 were made under the Misuse of Drugs Act 1984 and classify controlled drugs into five schedules with different controls applying to each schedule. The effect of the Regulations is to impose restrictions on the production, supply, importation and exportation of the drugs in question, which vary according to the extent to which these drugs are used for medical or scientific purposes and having regard to the likelihood of their being abused.

Appropriate exemptions are provided to cover legitimate use for professional purposes by doctors, pharmacists etc. and in other specified circumstances. In addition to these controls the Regulations specify the classes of persons who may have controlled drugs in their possession and the circumstances in which such possession would not be in contravention of the Act.

The pharmacist is one such person who is permitted to be in possession of controlled drugs in their professional capacity and who is responsible for the safe supply of controlled drugs to patients. They must strictly adhere to the requirements in the legislation in order to ensure appropriate supply and correct usage of these controlled drugs, therefore assuring patient safety.

The Regulations contain other miscellaneous provisions such as requirements as to the

- form of prescriptions for controlled drugs
- keeping of books and records
- arrangements for destruction or disposal of such drugs
- provisions regarding possession of forged prescriptions.

The Misuse of Drugs Regulations 1988 were amended in 1993 to improve documentation procedures in relation to exportation of controlled drugs and to change the level of control applicable to certain controlled substances.

Misuse of Drugs (Amendment) Regulations 2014

Most recently, the Misuse of Drugs Regulations were amended to provide for the lawful prescribing and dispensing of certain authorised medicines in certain prescribed formulations described in the regulation containing “an extract of cannabis” as well as changes to the rules for prescription writing for Methadone.

2.3.7 Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998

The principal legal requirements governing the supply of methadone and the provision of related services are contained in the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998. It is an offence to supply methadone otherwise than in accordance with these regulations. The pharmacist must act in compliance with these legislative requirements to ensure the patient’s welfare is protected. The specifications outlined in the regulations include, a pharmacist can only supply the specified controlled drug methadone on foot of a special methadone prescription form, to a person who has a valid treatment card.

2.3.8 Health (Pricing and Supply of Medical Goods) Act 2013

The Health (Pricing and Supply of Medical Goods) Act 2013 was implemented in June 2013 and provides much greater access to generic medicines in Ireland and aims to reduce medicine costs for patients and for the State. The Act introduces a system of generic substitution and reference pricing which allows patients to opt for lower cost interchangeable (i.e. generic) medicines. It also establishes a list of prescribed items which may be supplied or reimbursed by the HSE to patients under State drugs schemes, and establishes mechanisms for setting the prices of those items.

2.3.9 European Communities (Animal Remedies) (No.2) Regulations 2007

The European Communities (Animal Remedies)(No.2) Regulations 2007 were established under the Animal Remedies Act 1993 & 2007. The regulations set out detailed rules regarding the authorisation of animal remedies as well as the manufacture, importation, wholesale and retail sale of animal remedies. The regulations also include rules for the administration of animal remedies and certain matters relating to veterinary practice in relation to animal remedies.

The controls applicable to the authorisation, use and control of animal remedies ensure that the supply chain for a veterinary medicine from manufacture to delivery and subsequent use by the farmer or Veterinary Surgeon is regulated in the interest of the health, safety and welfare of animals and the public, as well as environmental safety. All animal remedies must be authorised by either the Irish Medicines Board or by the Minister for Agriculture, Food and the Marine as appropriate.

Pharmacies involved in the sale and supply of animal remedies are required to adhere to specific practices detailed in the legislation. First of all, the manner in which an animal remedy is sold or supplied depends on its supply classification as there are certain restrictions as to who can lawfully sell or supply such medicines. Pharmacies which are involved in the sale or supply of veterinary medicines must be aware of the veterinary product classification and may only sell the product in the appropriate manner in accordance with the legislation. Where such medicines are classified prescription-only they must be sold or supplied by the pharmacy, under the supervision of a pharmacist in accordance with a veterinary prescription which has been written in accordance with

all relevant legislative requirements. There are provisions for the supply of prescription-only veterinary medicines without a prescription in certain emergency circumstances which are also set out in the regulations. The regulations also require that the prescription itself is marked or endorsed in a particular way by the pharmacist after dispensing.

The regulations also provide that a veterinary surgeon can request the supply of veterinary medicines from a pharmacist for his/her practice. In such cases, the pharmacist who supplies such medicinal products must satisfy him/her, in so far as is possible, that the medication will be used appropriately. Finally, veterinary medicines should be stored separately from human medicines in the pharmacy to ensure that the risk of cross contamination between the two types of medicines is minimised.

2.3.10 Poisons Act 1961 & 1977

The Poisons Act 1961 provides for the establishment of a Poisons Council known as Comhairle na Nimheanna and defines its functions. The Act also provides for the regulation, control of distribution, transport, storage and sale of poisons and of the manufacture of pharmaceutical preparations containing poisons and of the use of poisons for agricultural and veterinary purposes.

Poisons Regulations 2008

The Poisons Regulations 2008 which were signed by the then Minister for Health and Children in December 2008, consolidate and replace the previous legislation i.e. Poisons Regulations of 1982. These regulations were established under the Poisons Act 1961 & 1977. The purpose of the regulations include, designating certain substances as poisons, outlining the personnel who are permitted to sell poisons and the premises on which poisons can be sold. The regulations also specify the requirements in relation to the sale and supply of poisons.

The Regulations provide that the retail sale of certain poisons (i.e. those specified in Part 1 of Schedule 1) may only take place at retail pharmacies by or under the supervision of registered pharmacists or registered druggists. The Regulations also provide that certain other poisons (i.e. those specified in Part 2 of Schedule 1) may be sold by retail outlets licensed for that purpose, as well as through pharmacies. The requirements for the recording of sales of scheduled poisons are set out in the Poisons Regulations 2008. Schedule 5 sets out the form of entry to be made in a record book to be kept in accordance with the regulations.

3 ANALYSIS OF CURRENT PSI INSPECTION POLICY AND INSPECTION PROCESS

A key element of this strategic review was to conduct an analysis of the current PSI inspection policy and inspection processes. This section comprises two sections – an overview of the current PSI Inspection Policy and Inspection Process and the results of the research conducted as part of the review of the current inspection policy for routine pharmacy inspections.

3.1 Overview of the current PSI Inspection Policy and Inspection Process

Section 7 of the Pharmacy Act 2007 places an overarching obligation on the PSI to supervise compliance with the Act. The Act provides for the general powers of inspection and investigation under Section 67 and specific authority to conduct an inspection as part of the process for the registration of a retail pharmacy business under Section 19.

The Inspection and Enforcement (I&E) Unit of the PSI is responsible for conducting inspections of pharmacies and for the registration of retail pharmacy businesses. The Head of the Inspection and Enforcement Unit, who reports to the Registrar of the PSI, established the unit in late 2008 and is responsible for a team of six[2] Authorised Officers[3] who conduct inspections of pharmacies registered with the PSI under the Pharmacy Act 2007.

All PSI Inspectors have experience in pharmacy practice and/or inspection/audit. Under Section 67 of the Act, Authorised Officers have powers of entry, search and seizure, power to inspect and take copies of books and records, to take samples and to seize evidence. Additionally, Section 19 of the Act allows Authorised Officers to inspect retail pharmacy premises with regard to applications for registration.

In accordance with the current PSI Inspection and Enforcement Policy Document, the objectives of the PSI inspection function are to promote good and safe pharmacy practice within retail pharmacy businesses. The PSI also aims to improve the delivery of pharmacy services and the standard of operation of these entities, and promote and ensure high standards of voluntary compliance with legislative requirements, PSI guidelines, best practice requirements and the PSI Code of Conduct for Pharmacists. A copy of the current PSI Inspection and Enforcement Policy Document is included in Appendix 3.

Conducting inspections is a key mechanism used by the PSI to fulfil its remit as a regulator and ensure that all pharmacies are operating in a manner which ensures patient safety and public protection. Through their work, PSI Inspectors provide assurance to both the Council and the public that each pharmacy is operating in accordance with the law and good practice.

Since its establishment in 2007, in accordance with the legislation and current policy provisions, the I&E Unit of the PSI has been conducting three main types of inspections:

[2] As at 1 October 2014, there are 6 full time Inspectors involved in conducting inspections.
[3] All Inspectors are Authorised Officers.

- Registration inspection (Section 19)

  Before it may lawfully commence operation, a pharmacy must be registered with the PSI in accordance with statutory rules (Pharmaceutical Society of Ireland Retail Pharmacy Businesses (Registration) Rules 2008). There is provision in these rules that the PSI may conduct an inspection of the premises as part of the registration or continued registration processes and the vast majority of new retail pharmacy businesses undergo an inspection as part of their registration process. This inspection must be notified in advance[4].

  This inspection assesses compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No 488 of 2008) and PSI guidelines. Inspectors verify that all essential procedures and equipment are in place to ensure that the pharmacy is set up to be operated in compliance with the law and current PSI guidance from day one of its operation. Inspectors also review the layout of the premises to ensure that it meets the legislative requirement to enable the supervision by the pharmacist of the sale and supply of medicines as well as the provision of a suitable consultation area on the premises for use by the public.
- Regular/Systems inspection (Section 67)

  Section 67 gives extensive powers to Authorised Officers of the PSI to conduct inspections and investigations for the "purposes of ascertaining whether any offence under the Act, any breach of a code of conduct or any professional misconduct has been committed or for obtaining information or evidence about these matters".

  To date the majority of pharmacy inspections conducted by the PSI have been conducted under this provision, the aim of which has been to provide assurance that the main systems, staff and structures are in place in all community pharmacies. There is no requirement in the legislation obliging the PSI to notify in advance of an inspection conducted under Section 67 and in accordance with the current PSI inspection policy[5], the decision to notify is at the discretion of the PSI. The principal reasons[6] for conducting these inspections on an unannounced basis under the current policy are:
  - To provide assurance to the public that the regulatory system for pharmacists and pharmacies is robust and is in the interests of patients and the public
  - To obtain an accurate assessment of the management of the pharmacy and its compliance with pharmacy and medicines legislation, on a day-to-day basis as experienced by patients.
- Investigation (Section 67)

  The PSI also conducts investigations under the authority of Section 67 of the Act. Investigations are usually directed by the Head of the I&E Unit or the Registrar of the PSI arising from receipt of a piece of information from a source (member of the public, healthcare professional, another pharmacist, etc.) or arising from a routine inspection by a PSI inspector. Investigations typically focus on a specific aspect(s) of the pharmacy.
- The PSI also carries out joint inspections or investigations with other statutory bodies under Section 67. The PSI engages with organisations such as the Health Products Regulatory Authority (HPRA), An Garda Siochána, The Health Service Executive (HSE) and the Department of Agriculture, Food and Marine.

[4] The requirement to notify is set out in Rule 5 of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses)(Registration) Rules 2008.

[5] Inspection and Enforcement Policy Document 2013

[6] Inspection Policy on Announced/Unannounced Inspections: PSI January 2014

The following table provides a summary of activity in the I&E Unit from 2009 to 2014 (Cycle 1):

Year	Registration Inspection	Routine Inspections	Investigations
2009	65	224	15
2010	64	280	33
2011	95	170	44
2012	97	75	28
2013	83	388	27
2014[7]	73	525	12

By the end of 2014, the PSI will have conducted either a registration inspection or a routine inspection in every registered community pharmacy in the State, thus concluding Cycle 1 of PSI Inspections.

3.2 Routine Pharmacy Inspections (Regular/Systems Inspection)

The PSI carries out routine compliance inspections known as "Regular/Systems inspections" of pharmacies under the authority of Section 67 of the Pharmacy Act. These types of inspections may be notified or un-notified[8]. Appendix 4 includes a copy of the current checklist used by PSI inspectors in conducting this inspection.

3.2.1 Scope of the PSI Regular/Systems Pharmacy Inspection

To date, Inspectors have conducted Regular/Systems Pharmacy Inspection only in community pharmacies and not in hospital pharmacies due to a lack of clarity as to the nature of the standards to be applied in such settings. This will be addressed by the PSI in 2014/5.

During the Regular/Systems Pharmacy Inspection, Inspectors focus on reviewing the records and documents required to be maintained by the pharmacist in accordance with the relevant medicines and pharmacy legislation. Inspectors also examine the prescription records to establish that the medicines which have been dispensed were done so in accordance with the legislation. Secondly, inspectors focus on examining the physical pharmacy premises and equipment at the pharmacy.

The overall aim of this approach is to provide assurance that the necessary systems, staff and structures are in place in each pharmacy. Furthermore, the review and examination of prescriptions and records at the pharmacy also facilitates the assessment of the manner in which pharmaceutical care is delivered at the pharmacy.

Additional aspects were added to the Regular/Systems Pharmacy Inspection over the course of Cycle 1 e.g. the examination of records and systems in place for the administration of the Seasonal Influenza Vaccine were introduced into the inspection process once pharmacists were lawfully enabled to commence this service in October 2011.

[7] Correct as at 30 September 2014.
[8] The decision to notify is at the discretion of the PSI in line with current policy.

Review of records

National pharmacy and medicines legislation is very prescriptive in setting out the requirements to maintain certain records and documentation at a pharmacy. The current inspection process has therefore been structured around these legislative requirements. A review and examination of pharmacy records provides evidence to the Inspector that what was done was done correctly and safely for the patient.

The following records are routinely requested and examined by the Inspector during an inspection:

- Duty register
  This is a record of the names of the pharmacists who provided professional cover at the pharmacy for each day that the pharmacy was open and operational. Inspectors review this record to verify that it is being completed correctly in accordance with the legislation.
- Prescription Register
  This is a record of the medicines dispensed by the pharmacy on each day that it was open and operational. This record must be retained at the pharmacy for 2 years from the date of the last entry. Inspectors review this record to verify that it contains all of the required information in accordance with the legislation.
- Controlled Drugs Register
  Every pharmacy is required to maintain a record of all incoming and outgoing supplies of certain controlled drugs (such as Morphine, Oxycodone etc.). Inspectors review the register to verify that it is being completed correctly. A key element of this record is the maintenance of the running balance in respect of each Schedule 2 controlled drug in the pharmacy safe. Therefore, as part of their review of the CD register, Inspectors also check that the running balance accurately reflects the actual quantity of dosage units in the pharmacy.
- Invoices
  Pharmacies are required to maintain all invoices for Controlled Drugs at the pharmacy for 2 years. Inspectors may also request to review the invoices as part of their review of the CD register to verify that the record is being maintained correctly.
- Dispensed Prescriptions
  Once fully dispensed, the pharmacy is required to retain the prescription at the pharmacy for 2 years. In the course of their review of the Prescription Register and Controlled Drugs Register, Inspectors review a number of prescriptions to ensure there is a legitimate and valid basis for the safe supply of prescription only medicines (POM), including controlled drugs (CD) recorded in the prescription and controlled drugs registers. Inspectors will check that in each case the prescription was valid at the time of dispensing and that the prescription has been marked correctly with the dispensing information. Inspectors may also request sight of the patient records to ascertain that intervals of dispensing were in accordance with the prescription. Where applicable, Inspectors will also check that the provisions in the legislation permitting the supply of a prescription only medicine without a prescription i.e. the Emergency Supply[9] provisions have been adhered to.

[9] Regulation 8 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended provides for the supply in certain circumstances of certain prescription only medicines without a prescription.

- Standard Operating Procedures (SOPs)
  There is a requirement for the pharmacy owner to maintain procedures for the storage, preparation, dispensing, compounding, sale and supply of human and veterinary medicines which are stored, prepared, dispensed, compounded, sold and supplied in the pharmacy to avoid deterioration of those medicines. Inspectors expect to find a set of written procedures in the pharmacy describing how certain tasks are to be carried out and which are used on a daily basis. In addition, the Inspector will be able to check that there are sufficient procedures in place to cover the activities that the pharmacy is engaged in. The Inspector will also check to see that the SOPs have been approved by the Superintendent Pharmacist and Supervising Pharmacist and that all relevant personnel have been trained in the detail contained within the SOP. Under the current processes, Inspectors do not routinely audit the SOPs in place at the pharmacy to verify that the procedures that are carried out at the pharmacies are in accordance with the procedure that is described in the SOP
- Veterinary Records
  Where relevant, Inspectors check that the records for all purchases and sales of all animal remedies (except companion animal remedies), prescriptions, requisitions, emergency supplies (supplies of prescription only medicines without a prescription) must be maintained in the pharmacy.
- Nursing Home Records
  The sale and supply of medicines to patients in nursing homes or residential care settings are examined to verify that medicines are safely supplied in accordance with original prescriptions, which were reviewed by the pharmacist prior to supply. Inspectors review the procedures and records governing the supply of medicines, the use of prescriptions, patient counselling and medication use reviews to ensure that patients in nursing homes or residential care facilities receive the same level of professional care as those patients who present in person at a pharmacy.

Review of pharmacy premises and equipment

The second focus of the pharmacy inspection is the pharmacy premises in order to ensure it is fit for purpose as a healthcare facility engaged in the sale and supply of medicines to the public. Inspectors examine the public part of the pharmacy to verify that it is clean, well presented and allows for convenient access by the public. They also check that the Patient Consultation Area, as provided for in the Regulation of Retail Pharmacy Businesses Regulations 2008, is located in the public area of the pharmacy and is convenient and accessible to the public, and that it complies with the law and guidance issued by the PSI.

In addition, as patients and the public do not have access to the dispensary or other storage areas of the pharmacy, inspectors will also look specifically at the manner in which medicines are being stored in these areas to ensure that all of the medicines in the pharmacy are stored in an appropriate manner. Many medicines have very specific storage requirements which have been defined by the manufacturer. Therefore it is imperative that the conditions of storage of each medicine in the pharmacy is suitable and will not compromise the quality of the medicines concerned. Inspectors also check that all of the medicines are stored in the part of the premises which have been registered with the PSI. Inspectors will also check that there is a system in place to ensure that any medicines which have been returned to the pharmacy by a patient are not

reintroduced into the 'live' stock in the pharmacy and that they are disposed of safely and appropriately. Inspectors will also check that records of the temperature of any refrigerators in use for the storage of cold-chain medicines are maintained at the pharmacy to verify that these critical medicines are stored appropriately.

Inspectors may also examine the other equipment in the pharmacy including tablet counters and electronic balances to ensure that they are clean, fit for purpose and, where necessary, calibrated.

3.2.2 Regular/Systems Inspection Findings

In 2014, the PSI published a summary of the inspection findings from the 388 Regular/Systems inspections conducted by the I&E Unit in 2013 in the PSI e-newsletter and PSI website. The summary included data in relation to the following topics:

- quality management systems
- supply of medicines to patients in nursing homes/residential care settings
- pharmacy premises and medicines storage
- supply of Prescription Only Medicines
- management of Controlled Drugs

The compliance rates under each of the above headings are set out in Appendix 5.

3.2.3 Scheduling of PSI Regular/Systems Pharmacy Inspections

Inspections in Cycle 1 were scheduled mainly on the basis of perceived risk to patient safety. Throughout the course of Cycle 1 the PSI engaged the services of Specialist Surveyors to conduct mystery shopper type activities and report back to the PSI. The PSI also receives information from a number of sources including members of the public, medical and healthcare professionals and other pharmacists.

All information received was collated and assessed by the Head of the Inspection and Enforcement Unit on the basis of the perceived risk to patient safety. Inspections were prioritised based on the apparent risk to patient safety arising from the risk assessment. The scheduling of each inspection was approved by the Head of the Inspection and Enforcement Unit prior to an inspection being conducted by the assigned Inspector.

In the absence of any information or intelligence which was deemed to impact the perceived risk of a pharmacy, inspections were scheduled on the basis of the geographical location of the pharmacy. In the interest of achieving efficient use of Inspector's time, inspections were scheduled for pharmacies which are located in a particular area or on a particular route.

3.2.4 After the Inspection - Reporting of Findings & Implications

Once the Regular/Systems inspection is completed, the Inspector prepares a report on the findings from the inspection which is issued to the Superintendent Pharmacist for the pharmacy. The report identifies non-compliances observed during the inspection and any required actions which must be undertaken in order to comply with legislative requirements and/or relevant guidelines. Under the current process, the inspected party has approximately one month to reply with confirmation to the

PSI that the required actions have been implemented. The vast majority of Regular/Systems inspections were closed on this basis.

In circumstances where serious and/or recurrent breaches of legislation, the Code of Conduct for Pharmacists or PSI Guidelines are identified during an inspection, the incidences of non-compliance will be considered in accordance with the provisions of Section 71 of the Pharmacy Act which provides that the Council shall consider the Inspector's report arising from the inspection conducted under Section 67 of the same Act. Certain options available under this provision have been delegated to the Registrar and include:

- Take no action;
- Commence disciplinary proceedings against pharmacists and/or pharmacies. This involves making a complaint against the relevant pharmacist and/or pharmacy;
- Take such other action as it considers appropriate in the circumstances. To date, this has included the following:
  - Seeking undertakings from pharmacists and /or pharmacies in relation to various aspects
  - Initiate district court proceedings under the Pharmacy Act 2007 or the Irish Medicines Board Act 1995 (as amended) in the name of the Council of the PSI. District Court proceedings are taken in the case of serious or recurrent non-compliance breaches. The PSI publishes the outcomes of the prosecutions on the PSI website
  - Refer the file to another relevant agency e.g. An Garda Siochána
  - Direct that a follow up inspection is carried out at the pharmacy to verify that the remedial actions confirmed in writing have been carried out.

3.2.5 PSI Resources for Regular/Systems Inspections

The I&E Unit also developed a number of resources made available on the PSI website to assist pharmacists and pharmacy owners in their preparation for a pharmacy inspection. The Inspection and Enforcement section of the website outlines general inspection information including the types of inspections carried out an overview of what they entail and the circumstances under which each is carried out. A Guide to Inspections was developed and a podcast to present the main elements of the inspection process, the expected length of the inspection and next steps after the inspection.

Inspection checklists were also prepared for each type of inspection. These checklists are identical to the checklist that the Inspector uses during the inspection and were intended to assist the pharmacist or pharmacy owner to complete a self-assessment of their pharmacy in preparation for any future inspection.

A section of the PSI monthly e-newsletter entitled "Inspectors' Advice on Improving Compliance" was also developed and made available on the PSI website. These articles provide advice from Inspectors on how to improve compliance in certain areas and aspects of practice based on the findings from inspections.

Other useful documentation, such as the PSI's Pharmacy Practice Guidance Manual, guidelines issued by the PSI to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008, and other practice notices and guidance issued by the PSI is available on the PSI website in the Pharmacy Practice section.

The I&E Unit has invested much time and resources over the course of Cycle 1 to streamline and improve its inspection processes. The implementation of the I&E Case Management System has played a key role facilitating the collection of inspection data, streamlining report writing and tracking responses from pharmacies. The Case Management System has also facilitated the reporting and analysis of various statistics by the I&E Unit.

Over the course of Cycle 1, the I&E Unit built up a considerable volume of data arising from the inspections and investigations conducted. This data is very important in building risk profiles for each of the pharmacies in the State.

3.3 Results of the Research Conducted

As part of the strategic review, a number of pieces of research were conducted to gather views on the current policy for PSI Routine Pharmacy Inspections as follows:

- Survey 1 and Survey 2 of pharmacists, pharmaceutical assistants and pharmacy owners
- Questionnaire issued to PSI Authorised Officers
- Invitation issued to key national stakeholders

The Group also invited the Head of the I&E Unit to make a presentation on the current process for routine inspections at meetings of the Expert Group on 12 September 2014.

3.3.1 Survey of pharmacists, pharmaceutical assistants and pharmacy owners

Methodology

Two separate surveys were designed to obtain feedback from pharmacists, pharmaceutical assistants and pharmacy owners. The surveys were issued through a survey tool, "Survey Gizmo", to facilitate the collection of anonymous feedback in relation to key aspects of the current inspection policy and process.

Survey 1 was designed for those who have experienced a PSI inspection and Survey 2 for those who have not experienced a PSI inspection or are not likely to be inspected (by virtue of their area of practice). Electronic versions of the two surveys were issued on Friday 25 July by email to all registered pharmaceutical assistants as well as all registered pharmacists and pharmacy owners. Hard copy versions of the two surveys on current PSI inspection processes were issued on 30 July to those pharmacists, pharmacy owners and pharmaceutical assistants who, according to our Register, do not have an email address. The survey closed on Monday 11 August. In total, 598 respondents participated in the two surveys[10].

Survey 1, for those who have experienced a PSI inspection, comprised 13 questions. The first series of questions aimed to establish the role and area of practice of the respondent and the type of inspection they had experienced, i.e. whether it was a New Opening inspection or a Regular/Systems inspection or both. Respondents were also asked to rate their own knowledge of the current

[10] 585 participated in the electronic surveys (430 – Survey 1, 156 Survey 2), 13 participated in the hard copy surveys (9 – Survey 1, 4 – Survey 2).

inspection process, how they prepare for an inspection and to provide their comments or feedback in relation to the current inspection processes.

Survey 2, for those who have not experienced a PSI inspection or are not likely to be inspected by virtue of their area of practice, comprised 5 questions. As for Survey 1, the first series of questions aimed to establish the role and area of practice of the respondent. The Survey also provided an opportunity for respondents to provide their feedback on the resources they think might be helpful for preparing for inspection and other feedback on the current inspection processes.

Copies of Survey 1 and Survey 2 are included in Appendix 6.

Once the surveys were closed, the results and responses were analysed. Different question formats in the survey required different methods of analysis. The reporting function on Survey Gizmo provided the total number of respondents and the results of the multiple choice questions in percentages.

In order to analyse this qualitative data, each comment was analysed individually and categorised. As a participant may have made multiple points in one comment, the figures set out in the results are not cumulative and it is not possible to reconcile them with the total number of responses.

Overview of results

Appendix 7 includes a detailed analysis of the results from Survey 1 and 2. The following is a summary of the results.

Roles and areas of practice

The majority (75%) of respondents to Survey 1 were working in an independent pharmacy or in a group of less than five pharmacies in a community pharmacy practice setting with 24% and 1% respectively working in either a community pharmacy group practice or hospital pharmacy. The majority of respondents were working as Superintendent or Supervising Pharmacists.

The areas of practice for the respondents to Survey 2 was broader with 18% of respondents working in a hospital pharmacy setting and a further 8% working in academic and industry settings. The majority of the remaining respondents were working in a community setting (51% independent or group less than 5 pharmacies and 27% in a group more than 5 pharmacies). Whilst the majority of respondents were working as Superintendent or Supervising Pharmacists (23% and 33%), responses from hospital pharmacists and locum pharmacists were higher in this group of respondents.

The roles and areas of practice of the two groups of respondents reflect the fact that the majority of inspection activity to date has been in the community pharmacy setting.

Rate knowledge of the PSI's Inspection and Enforcement function

Over 75% of respondents to Survey 1 self-assessed their knowledge of the PSI's Inspection and Enforcement function as being good or very good with less than 1% indicating they had no knowledge of the PSI's Inspection and Enforcement function. This data demonstrates the level of engagement and understanding that the profession feel they have with the current inspection

processes. The knowledge profile of respondents to Survey 2 was slightly different with the majority of the respondents (73%) indicating that they have some or good knowledge of the PSI Inspection and Enforcement function.

Overall, as expected, a higher level of self-assessed knowledge of the inspection process was observed in those who had experience of an inspection.

Feedback on Regular/Systems Inspections

The results from Survey 1 indicate that over 70% of the respondents felt that the regular/systems inspection was what they had expected and almost 65% of respondents felt adequately prepared for the regular/systems inspection.

204 respondents made 501 individual comments in relation to the regular/systems inspection. Each comment was reviewed individually and categorised as either positive or negative. In addition, in reviewing the comments, it was noted that a high number of respondents made comments relating to announcing Regular/Systems inspections.

The following is a summary of the top ranking comments made under each category:

- Positive Comments
  - positive comment on the conduct of the inspector
  - PSI/IPU checklists/self-audits were helpful in preparing for the inspection
  - inspection process was thorough/fair
- Negative Comments
  - difficult to conduct the business of the pharmacy during the inspection
  - the inspection process was too detailed/focussed on regulation
  - the inspection process was focussed on finding fault with no acknowledgement of good practice
  - inspection process should be about providing advice and not punishing/adversarial
- Announcing Regular/Systems Inspections
  - inspections should be announced to ensure adequate staffing during the inspection
  - an announced inspection would allow time for the pharmacy to prepare and have everything in order
  - inspections should be announced (no reason why provided)

Question 5 of Survey 2 asked respondents to provide their comments on the current PSI inspection process. A total of 54 comments were submitted in response to this question. The top ranking comments were as follows:

- inspections should be announced to ensure that there is adequate staffing in the pharmacy for the inspection
- the inspection process should be different for community and hospital pharmacies/need guidance for the inspection of hospital pharmacies
- provide regular feedback on inspection findings.

Feedback on New Opening Inspections

For completion, a section was included in the survey on new opening inspections (conducted under Section 19 of the Pharmacy Act). In total 27% of respondents to Survey 1 provided their feedback on the current inspection process. The results indicate that 74% of the respondents felt that the New Opening inspection was what they had expected and almost 82% of respondents felt adequately prepared for this type of inspection.

61 respondents made 116 comments in relation to the New Opening inspection process. Each comment was reviewed individually and categorised as either positive or negative with the majority of comments indicating that the inspection process was straightforward/thorough.

Preparation for an inspection

Respondents to Survey 1 were asked which PSI resources they use to prepare for an inspection. The following is a breakdown of the results:

- 62% indicated that they visit PSI website
- 76% indicated that they use the PSI self-assessment checklist
- 35% indicated that they read the PSI Newsletter articles
- 33% indicated "other". A total of 66 comments were received under the heading "other" and included IPU website/Self Audit, Internal Company Checklist and Advice from colleagues/word of mouth.

These figures were in line with the responses to the question in Survey 2 which asked respondents which PSI resources they thought would help pharmacists and pharmacy owners to understand the current PSI inspection processes.

Finally, respondents to Survey 1 indicated that the PSI should provide the following additional resources to help prepare for an inspection:

- publish recent findings from inspections
- announce inspections in advance - 36 comments
- publish detailed inspection checklists or guidelines

3.3.2 Questionnaire Issued to PSI Authorised Officers

Methodology

In order to elicit feedback from the PSI Authorised Officers currently engaged in conducting Regular/Systems Inspections, a questionnaire was designed. A copy of the questionnaire is included in Appendix 8. The questionnaire comprised 11 questions and the Authorised Officers were asked to complete it anonymously and the responses to the individual questions were analysed.

Analysis

The following is a summary and analysis of the responses received.

Duration of the Regular/Systems Inspection

On average it takes the Authorised Officer 2 hours to complete the inspection. The Authorised Officer engages with the pharmacist for approximately 30 minutes over the course of the inspection, comprising of roughly 10 minutes at the beginning of the inspection and 20 minutes towards the end of the inspection to gather specific information or ask the pharmacist questions and provide feedback on the inspection.

Factors that affect ability to interact with the pharmacist over the course of the inspection

The Authorised Officers were asked about factors that affect their ability to interact with the pharmacist over the course of the inspection. Most of the comments made related to the availability of the pharmacist to the inspector and the level of activity in the pharmacy over the course of the inspection. It was also noted that the attitude of the pharmacist to the inspection process, their familiarity with the process and their willingness to interact with the Authorised Officer were factors which affected the inspection process for the Authorised Officer.

Factors that make inspection process easier to conduct

The Authorised Officers were also asked what makes the process easier for them when conducting the inspection. The answers included, the level of the pharmacist's knowledge/familiarity of the inspection process, describing the inspection format to the pharmacist before commencing the inspection, good organisation in the pharmacy, if the premises are well maintained, adequate staffing and cooperation from the pharmacist. The inspection process is also made easier when there is generally a high level of compliance with legislative requirements and guidance at the pharmacy and if the supervising or superintendent pharmacist is present during the inspection.

Familiarity with PSI website and newsletter & Use of checklists/self-inspection

The Authorised Officers were asked in general how familiar pharmacists are with the inspection process and whether pharmacists/owners refer to the PSI website or the Newsletter (Inspectors' advice). The responses were consistent in that there were varying degrees of familiarity with the inspection process, some pharmacists or owners were very familiar while others were very unfamiliar. It was found that many pharmacists are not familiar with the PSI website or the inspection advice segment of the newsletter, but some have gone through the PSI checklists. Most are also not familiar with the guidance that has been issued in relation to certain topics, all of which are available on the website. Many Pharmacists are surprised at the increased level of inspection activity that is now occurring and some state that they have been expecting an inspection.

The questionnaire also asked the Authorised Officers if there was evidence that pharmacists or owners were using the checklists or conducting self-assessments in preparation for the inspection and if this has an impact on the inspection process. The Authorised Officers found that in some pharmacies the PSI or IPU checklist is included in the SOP folder and it is clear it is being used. In the majority of pharmacies the checklist is included in the SOP folder however it is either not completed or the issues identified in the checklist have not been addressed.

Changes in inspection findings in recent years

The Authorised Officers were asked what changes they have noticed in inspection findings over the last number of years. They noted that there appears to be greater awareness in certain areas as a result of guidance documents, e.g. residential care homes, there is greater adherence to record keeping practices, there has been an improvement in the standard of pharmacy premises and equipment, pharmacists are generally more receptive towards routine inspections. However, they noted that in general, the awareness of the requirements for sale and supply of veterinary medicines was low. Standard Operating Procedures (SOPs) are now present in most pharmacies, however, it was noted that in general they are not being used as live documents to improve efficiency and guide practice in the pharmacy.

Feedback after inspection

The Authorised Officers reported that in general, they received positive feedback from pharmacists at the end of the inspection process. The common questions asked after an inspection include where to purchase certain equipment, what happens after the report is issued and what are the implications of the inspection. Questions in relation to re-inspections, financial implications of premises improvement and technical questions concerning dispensing procedures are also asked.

Additional comments

The Authorised Officers were asked to provide any additional comments they wished to make on the current PSI regular/systems inspection process. Authorised Officers indicated that the current process is a helpful education tool and ultimately can help identify any major concerns in pharmacy practice, while future inspections will establish if practices have changed and if compliance has improved since the initial inspection in Cycle 1. There were also some comments that the current inspection process does not provide for a review of all elements of pharmacy practice, e.g. whether the pharmacist is counselling/interacting with patients adequately, if the consultation area is appropriately used, or if services are being offered properly.

3.3.3 Responses from Key National Stakeholders

Key national stakeholders with interests in relation to the current PSI inspection policy were identified. They included, the Department of Health, the Health Service Executive (HSE), the Irish Pharmacy Union (IPU), Pharmacists in Industry, Education and Regulation (PIER) and the Hospital Pharmacists Association of Ireland (HPAI). Patient representative groups were also contacted. A full list of the national stakeholders contacted is included in Appendix 9.

Methodology

In order to engage with key national stakeholders, individual letters were issued to each of these organisations. A copy of the letter issued is included in Appendix 10. The stakeholders were also issued with a copy of the current PSI Inspection Policy and were invited to provide their comments before a specific date. It is important to engage with national stakeholders in order to seek comments, views and possible recommendations to ensure that any future developments in PSI Inspection Policy are in line with national practice.

Analysis

The following is a summary of the responses received:

Department of Health

- As part of the implementation of "Future Health: A Strategic Framework for Reform of the Health Service 2012-2015", the department is of the view that pharmacists will be expected to identify and contribute to implementing evidence based and cost effective solutions to ensure the effectiveness and sustainability of the healthcare system, by addressing key medicines issues such as medicines wastage, inappropriate usage of medicines, supporting and improving chronic disease management and patient adherence to medication. They are also responsible for addressing how the role of the pharmacist could be expanded.
- Pharmacists also have a role to play in delivering on the goals of "Healthy Ireland".
- The Department is of the view that any new inspection policy should reflect the broader nature of the current role of the pharmacist.
- Inspections should be undertaken in a manner which will underpin public health protection as well as support patient confidence. This requires that an appropriate proportion, at least, of routine inspections be carried out without prior warning, i.e. unannounced.
- The Department believes that the announced/unannounced nature of the inspection be at the discretion of the regulatory body.

Health Service Executive (HSE)

- The current PSI policy is comprehensive and appropriate in discharging a statutory role to protect health and safety of the public through regulation of pharmacies.
- It is important to retain a high incidence of unnotified inspections if the public protection element of the Statutory Regulator's responsibilities is to be discharged with appropriate rigour.
- For cross-agency inspections, which include PSI and HPRA and the HSE, it remains very important to conduct such inspections unannounced.

Irish Pharmacy Union (IPU)

The IPU submitted the following suggestions for a future model of routine PSI pharmacy inspections:

- One weeks' notice sent by email to both the Pharmacy Owner and to the Supervising Pharmacist, would be more appropriate to allow sufficient time to reorganise the pharmacy rota to ensure adequate attendance of the relevant staff on the day of the inspection, and even to be present themselves if they wished in order to cope with the additional work load involved in assisting the authorised officers' inspection of the pharmacy.
- It would also allow time for the pharmacist to review their documentation to ensure all appropriate relevant registers, records and other paperwork were available and easily accessible, rather than having to dig the various documents out on the day. One week's notice would not be sufficient to make a non-compliant pharmacy, compliant.
- Introduction of self-audit would result in inspections being shorter; consequently, three inspections could be carried out per day.
- Pharmacies which submit confirmation of completion of the Self Audit Tool receive an announced follow up inspection and those pharmacies that don't, receive an unannounced inspection.

Patient Focus

- Inspection and investigation are vital tools in ensuring compliance with legislative requirements and promoting best practice in Pharmacy businesses and among pharmacy professionals.
- Patient Focus welcomes the use of both announced and unannounced visits to pharmacies in the exercise of these functions. Both are vital tools for examining different aspects of a business or a professional's performance in relation to patient safety.
- Noted that inspections are based on perceived risk. How are these perceived risks established and monitored in individual businesses and particular professionals performance? We believe a proactive approach is best suited to establishing risk rather than reliance on complaints or adverse incidents. This document is part of this process. Self-assessment of risk by businesses and professionals is important here. Good communication channels between providers and the PSI is important in relation to feedback and learning here. In this context we are supportive of checklists, guidelines of international standards etc.
- The views of non-professional staff, consumers and the public need to be proactively sought as a normal part of on-going monitoring. Mystery shoppers help here. Perhaps a forum for the expression of views by consumers /or the general public would be helpful.
- We believe the protection of the public is best served by ensuring the inspection by the PSI of all start up potential pharmaceutical providers before business commences.
- We would be most supportive of the practice of random and targeted, in-depth follow up inspections where remedial actions have been necessary.
- In addition inspection reports should be published as in the case of nursing homes on the HIQA website. Incidents of best practice can also be used as a means of encouragement and mentoring to others.
- The investigation process is a disciplinary process and it is important that patients/consumers/lay people have a central role in triggering them, as adjudicators and as witnesses where appropriate. These too should be transparent, fair and patient safety focused while clearly complying with due process. Hearings in public as well as published decisions should be available.

Irish Cancer Society

- Stated that they did not have any comments they would like to make.

4 ANALYSIS OF NATIONAL AND INTERNATIONAL REGULATORY PRACTICE

As part of the review the Group also conducted research into regulatory and inspection policies of approximately 60 national and international pharmacy and non-pharmacy organisations.

The following paragraphs set out the research methodology and the analysis of the responses received.

4.1 Methodology

In order to ensure that the research generated a wide range of perspectives, a questionnaire was designed to elicit information on the regulatory and inspection policy in place in each of the following four groups of organisations[11]:

- National Healthcare Regulators
- National Healthcare Regulators with no inspection function
- National Non-healthcare Regulators/Bodies with inspection function
- International Pharmacy Regulators

Appendix 11 contains a list of the organisations identified under each group.

The questionnaire was issued to 56 national and international organisations by email. In addition, the questionnaire was issued by the office of the Permanent Representation of Ireland to the EU to the Health Attaches in Brussels for each of the European Member States requesting that they direct the questionnaire to the most appropriate colleague in their capitals.

A total of 26 organisations submitted a response to the questionnaire. Appendix 12 contains a list of the respondents.

The questionnaire comprised two sections – Section A and Section B. A copy of the questionnaire is included in Appendix 13.

Section A of the questionnaire dealt with the overall regulatory policy in place in the organisation and included questions on the legislative basis, operation and governance of the regulatory body. Section B of the questionnaire dealt with the particulars of the individual inspection policies in place in each organisation and included questions on the methodologies that regulatory bodies used to select entities for inspection, the inspection types conducted and the scope of the inspection processes and reporting on inspections.

4.2 Analysis

In light of the substantial amount of information provided in the responses to the questionnaires, the analysis was structured in two ways. Firstly, each response was analysed individually. It was noted that each response received provided substantial insight into the regulatory and inspection

[11] A number of organisations which are not regulators, but are involved in inspection/enforcement were invited to complete the questionnaire.

policies pursued by each organisation. Although this was very useful information, members of the Expert Group noted that as the general approaches to regulation were broadly similar, the details of the relevant legislative provisions were a key determinant in the exact regulatory and inspection policies pursued and there was no "one size fits all" approach to regulation or inspection.

Secondly, in order to conduct a structured analysis of the key areas of interest, the responses to the key questions were extracted and a summary prepared to provide an overview of the responses. A copy of this is included in Appendix 14.

The following is a detailed analysis of the responses received for each section of the questionnaire.

Section A

Responses provided to Section A of the questionnaire provided a general background and insight into the overall regulatory policies in place in each organisation.

Section A included questions on the following aspects of regulatory policy:

- Description of the regulated entities
- Legislative authority under which the organisation operates
- Description of the regulatory policy
- Arrangements for the oversight of the activities of the organisation
- Methodologies used by the organisation to review its effectiveness as a regulator
- Recent changes in regulatory policy

All 26 respondents stated that their organisations operate on a statutory basis, with each setting out the specific piece of applicable national legislation in their response. Respondents also provided details of the regulatory policy in place in their respective jurisdictions together with details of the entities they regulate. This was essential information to contextualise the responses to Section B of the questionnaire which related to inspection policies.

The Group noted that the regulatory policy set out in the Pharmacy Act for the regulation of pharmacists and pharmacies by the PSI is broadly consistent with the approaches to regulation taken in other jurisdictions.

Section B

Section B of the questionnaire sought feedback from respondents on a number of different aspects of the inspection policies in place including:

- Level of inspection activity, number of inspectors, qualifications of inspectors
- Intervals of inspection
- Notification of inspections
- Types of inspections conducted
- Role of self-inspection/self-audits
- Reporting on inspections
- Implications for the inspected party arising from an inspection

In analysing the responses to Section B, it was noted that all but 3 of the respondents conduct inspections under a statutory provision. As different regulators had different approaches to inspection, it was noted that a number of common themes emerged in the approaches to inspections described by the various organisations which were summarised under the following headings:

- Scheduling inspections – announced or unannounced?
- Using risk profiling to select entities for inspection
- Using self-assessments as a basis for inspection
- Outcomes focussed inspections
- Publication of inspection reports
- Other observations from respondents which were of interest

Scheduling inspections – announced or unannounced?

12 out of 23 organisations indicated that they conduct a mixture of announced and unannounced inspections. A further 6 out of 23 and 4 out of 23 conduct announced and unannounced inspections only. The responses from the international pharmacy regulators indicated a general preference to conduct unannounced inspections or at most to provide an approximate period for inspection.[12]

12 out of 23 organisations announce inspections to ensure that the key personnel are available and present for the inspection. The Group noted that a number of Irish organisations in the healthcare area conduct announced inspections. In the cases of HIQA and HPRA in particular, meetings with key personnel in the facility being inspected form a very important part of certain inspection processes. However, in both cases, unannounced inspections may also take place.

Using risk profiling to select entities for inspection

The majority of organisations (16 out of 26) indicated that inspections are conducted at defined intervals over the course of an inspection period typically between 3 and 5 years in duration. Furthermore, 16 respondents indicated that inspections are scheduled on the basis of risk. It was also noted that profiling of the regulated entities was an important tool for the respondents to inform the manner in which they schedule or prioritise entities for inspection. The principle reason for this approach is to ensure that inspection resources were directed to those entities which presented the greatest perceived risk to the public. Organisations also reported that they used the information available to them to build a picture of the risks arising from the activities of the entities regulated. The Group noted the approaches of the following organisations in particular:

- The Alberta College of Pharmacists, Canada used data to risk profile and segment pharmacies into low, medium and high performing pharmacies on the basis of segmentation criteria including demographics; patient assessment; care plans, monitoring and follow up; documentation; patient safety programmes; history of complaints and a small component based on operations (staffing and cleanliness of the pharmacy). Criteria have been validated over the last four years.
- The Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI) noted that the nature of the deficits identified during inspections were used as a basis to vary the intervals between inspections.

[12] The reasons for not announcing inspections were not invited in the questionnaire.

- Pharmaceutical Services, Ministry of Health, Cyprus conducted inspections at different intervals depending on whether pharmacies store narcotics or not.
- HIQA stated that regulatory activity is risk based and targeted at those services deemed to be higher risk.

Outcomes focussed inspections

The Group noted that a number of authorities including the General Pharmaceutical Council, Alberta College of Pharmacists, HIQA and the Department of Education and Skills explicitly described an inspection model which was based on verifying outcomes in a more holistic manner rather than assessing compliance with specific rules/regulations/guidelines.

In the case of these two pharmacy regulators (the General Pharmaceutical Council (Great Britain) and Alberta College of Pharmacists), and HIQA, the inspection processes were centred on verifying that the processes in place in the regulated entities were actually achieving good and safe outcomes and experiences for the benefit of patients. In general, an outcomes focussed approach appears to provide more flexibility for the regulator in conducting its inspection activities. In addition, this approach also provides greater scope to the inspected party to demonstrate how it provides its services rather than merely demonstrating compliance. In the case of the Alberta College of Pharmacists, Canada the inspection focusses 80% on practice and 20% on operations.

Using self-assessment as a basis for inspection

20 organisations indicated that they utilise self-assessment by regulated entities as part of their regulatory toolkits. 10 out of 20 indicated that such self-assessment was mandatory and was reviewed during the inspection as part of the overall system of quality management in place.

Publication of Inspection Reports

The vast majority of respondents (20 out of 22) provide a report to the inspected party after the inspection. It appears from the responses provided that the inspection report is a key element of the inspection process; setting out the observations from the inspection and detailing any next steps arising from the inspection, and providing a mechanism for the inspected party to respond.

The Group noted that the Department of Health Social Services and Public Safety in Northern Ireland (DHSSPSNI) described a recent innovation in their processes whereby computer generated inspection reports are prepared on site during the course of the inspection.

The Group also noted that in general, international pharmacy regulators (8 out of 9) do not publish inspection reports. However, The General Pharmaceutical Council stated that it would be disposed to publishing summary inspection reports in the future, however a legislative change would be necessary first. In analysing the preferences of the national healthcare regulators, it was noted that there was a more even split in relation to the policy on publishing reports with 3 out of 6 publishing reports on their websites. Respondents did not provide the reasons for either publishing or not publishing.

Other observations from respondents which were of interest

The Group also noted the following observations from respondents:

- Pharmacy Council of Western Australia
  - As pharmacy community becomes more aware of the expectations of the Board, there has been a greater level of compliance
  - Self-audit is mandatory and is reviewed during inspections. Registrants are required to submit a Statutory Declaration at annual registration stating that self-audits have been completed.
- Alberta College of Pharmacists, Canada
  - Inspections are called pharmacy assessments. Inspectors are called pharmacy practice consultants.
  - Inspections assess practice and operations using an educational approach and attempt to coach pharmacy teams to standards.
  - Taking the time to build rapport and establish relationships with pharmacy teams has helped to enhance practice as they genuinely like the pharmacy practice consultants and are willing to make improvements to their practice.
- SUKL (Czech Republic)
  - One peer reviewed inspection per year per inspector
- Department of Education and Skills
  - Moved away from a cyclical approach to the inspection of schools to "smart" inspection which includes consideration of risk to students' outcomes in identifying schools for inclusion in that programme.
- It was also noted that SUKL (Czech Republic), HPRA and the Pre Hospital Emergency Care Council (PHECC) have achieved ISO 9001 (standard quality management system) for their own operations.
- Both the Offices of the Revenue Commissioners and the Central Bank of Ireland have developed electronic tools to assist in their risk assessments:
  - REAP – Risk Analysis and Profiling. Rates the risk of Revenue's customer base.
  - PRISM - Probability Risk and Impact System. Used by the Central Bank of Ireland as a risk based supervision framework used to regulate financial institutions. Firms are categorised into 4 distinct impact categories (high, medium high, medium low and low) based on the size of the firm and the degree of prudential or customer harm it would cause if they failed. On the basis of this information, the Central Bank of Ireland carries out themed inspections - specific risks and issues.

4.3 Other Regulatory Approaches of Note

The Group also noted some interesting approaches from the following two organisations which did not participate in the questionnaire:

- Care Quality Commission, England
- Health and Safety Authority, Ireland

The Care Quality Commission (CQC) is the independent health and adult social care regulator in England and is responsible for ensuring that the care provided by hospitals, dentists, ambulances, care homes and home-care agencies meets government standards of quality and safety. It also

works to protect the interests of vulnerable people, including those whose rights are restricted under the Mental Health Act.

In particular, the Group noted that the CQC is currently redesigning its inspection processes. The Group made specific reference to the Strategy Document 2013 to 2016 and noted the list of questions which CQC proposed as a framework for the redesign process which the Group considered to be a sensible and logical approach:

- Are the services safe?
- Are the services effective?
- Are they caring services?
- Are the services well led?
- Are the services responsive to people's needs?

Secondly, the Group noted the very robust approach of the Health and Safety Authority in relation to self-assessment. Specifically, the Group noted in particular the following aspects which have been provided for in the Safety, Health and Welfare at Work Act 2005:

- It places an obligation on every employer to identify hazards in the place of work under his or her control, assess the risks presented by these hazards and be in possession of a written assessment of the risks to the safety, health, and welfare at work of his or her employees
- It places an obligation on every employer to prepare a safety statement
- It places an obligation on every employer to appoint one or more competent persons to perform risk assessments and prepare safety statements.
- It creates an offence if the employer fails to inform the safety representative that an inspection is taking place.
- It creates a number of offences for the failure to co-operate with the inspection process and implement improvement and prohibition orders as directed by the HSA.

5 FINDINGS AND RECOMMENDATIONS

In line with its Terms of Reference and having regard to the research conducted and the experience within the group, the Expert Group examined the current model for routine pharmacy inspections by the PSI (Regular/Systems inspection), proposed a model for future routine inspections and proposed an implementation strategy for this model. The following paragraphs set out the findings and the associated recommendations from the Expert Group.

5.1 Current Regular/Systems Inspection

The Group acknowledged the important role of inspection in the PSI's regulatory toolkit in discharging its primary duty to protect and promote the health, safety and well-being of patients and the public.

The Group considered the purpose of conducting routine inspections in the context of the overall function of the PSI as the statutory pharmacy regulator in Ireland as set out in the Pharmacy Act 2007 and agreed that the purpose of a routine pharmacy inspection is to conduct an assessment or evaluation of the practices at the pharmacy against the current legislation and guidance to provide assurance to the PSI that patients and the public are provided with the appropriate care that is delivered to the highest standards of quality and safety every day that the pharmacy is operational.

The Group noted that the objective of the current Regular/Systems inspection was to provide assurance to the PSI that the main systems, staff and structures are in place in all pharmacies. The Group analysed the main achievements and advantages of the current process for routine inspections.

Achievements associated with the current process for routine inspections

- In the period January 2009 to December 2014, every community pharmacy will have received either a Registration Inspection or a Regular/Systems Inspection[13, 14].
- Since its establishment in 2008 by the current Head of the I&E Unit, the I&E Unit has grown from a team of 2 Inspectors to a highly functioning unit of 6 Inspectors with substantial collective experience in both pharmacy practice and inspection/audit.
- The Unit as a whole has accrued substantial experience and expertise in the area of the inspection of pharmacies and has gained valuable insight in to the practicalities and challenges of operating pharmacies.
- The Unit has developed a very comprehensive and user-friendly suite of documents to facilitate compliance by pharmacists with requirements and preparation for inspection.
- The aims of Cycle 1 were achieved, namely by:
  - identifying the baseline compliance in connection with the operation of retail pharmacy businesses

[13] In some cases, some pharmacies may have received both types of inspection.
[14] As at 30 September 2014, 2139 inspections have been conducted (Registration and Regular/Systems Inspections).

- identifying non-compliance trends and/or areas for improvement and to keep pharmacy owners and pharmacists informed of any practice or safety concerns observed
- Developing a risk assessment methodology in order to ensure more targeted intervention for high risk inspected parties.

- The I&E case management system was developed and has facilitated the standardisation and improved quality of inspection reports by automating many aspects of the report. This was a significant factor in increasing the efficiency of the inspection process. This system has also facilitated the retention and extraction of inspection data for the purposes of reporting of inspection statistics and informing PSI guidance documents. Arising from this, the Unit was able to publish the aggregate findings from Regular/Systems inspections conducted in 2013 in June 2014.
- Increased standards of compliance over the course of Cycle 1 and increased levels of awareness of the role of inspection within the overall role of PSI, based on the observations from the Inspectors.

Advantages associated with the current process for routine inspections

- The current Regular/Systems Inspection process has been in operation since 2012 and is now very well established.
- Pharmacists and pharmacy owners have become accustomed to this type of inspection and know what to expect.
- Inspections are unannounced which has facilitated PSI in obtaining an accurate assessment of the management of the pharmacy and its compliance with pharmacy and medicines legislation on a day-to-day basis as experienced by patients.
- The inspection process is very transparent, consistent and well-structured.
- The inspection process is very efficient and Inspectors can regularly conduct up to 3 Regular/Systems Inspections per day. In 2013, the I&E Unit conducted 388 Regular/Systems inspections and in 2014[15], 525 Regular/Systems inspections have been conducted.
- The broad scope of the Regular/Systems Inspection that includes a review of premises, equipment, records and prescriptions.
- A detailed report is issued after each inspection. The Superintendent and/or Supervising Pharmacist was obliged to respond to this report indicating that all observations made by the Inspector have been addressed and corrective actions implemented. The report has been a very important element of the inspection process in communicating the observations of the inspection to the Superintendent Pharmacist at the pharmacy. The Report has also been important in assisting the PSI to build a risk profile on individual pharmacies.
- Inspections are prioritised on the basis of an assessment of the perceived risk to patient safety or alternatively on the basis of geographical location to optimise the efficient use of Inspector resources. This is a flexible approach.

Overall, the Group agreed that the current Regular/Systems inspection model was sensible and straightforward and achieved its intended objective for the first cycle of routine inspections by the PSI under the new Pharmacy Act. It also agreed that there were many aspects of this model which were working well as regulatory tools for the PSI.

[15] Correct as at 30 September 2014.

Limitations associated with the current process for routine inspections

The Group also noted the following limitations associated with the current process for routine inspections:

- The model of inspection did not require the Superintendent/Supervising Pharmacists to maintain documentary evidence of the ongoing assessment of compliance with legislation and PSI guidance by the pharmacy.
- The requirement to have documented procedures at the pharmacy was a new requirement under the Pharmacy Act. Regular/Systems inspections conducted during Cycle 1 verified that these procedures were in place, but the inspection process did not challenge the procedures to verify that they reflected the actual practices at the pharmacy.
- The inspection process assessed the provision of pharmaceutical care principally though the examination of various prescription and Controlled Drugs registers and prescriptions. There was less focus on observing the interaction with patients and the manner in which the pharmacists and the other staff at the pharmacy provide pharmaceutical care and treatment and advice and relevant information to patients.
- The fact that routine inspections are currently unannounced means that key personnel such as the Superintendent or Supervising Pharmacist may not be present or available to participate in the inspection.
- The relevant provisions of the Health (Pricing and Supply of Medical Goods) Act 2013 are not currently included in the scope of the routine pharmacy inspection.
- To date hospital pharmacies which are registered retail pharmacy businesses have not received a routine pharmacy inspection.

Recommendation 1

The Group recommends that the PSI should adopt a new type of routine pharmacy inspection which addresses the limitations identified with the current Regular/Systems Inspection.

5.2 Proposal for a new inspection type for the future

Having regard to Recommendation 1 above, the Group then discussed a model which it believed addressed the limitations it identified with the current Regular/Systems inspection.

From the outset, the Group was cognisant that any proposal for a future inspection type would have to be compatible with the overall regulatory framework for the practice of pharmacy in Ireland set out in the Pharmacy Act and provide the appropriate assurance to the PSI that that the pharmacy inspected was providing a safe and effective pharmacy service to patients and the public. It also acknowledged that the future model would have to be sufficiently agile to keep pace with future pharmacy developments.

The Group noted that one of the key limitations in the current Routine/Systems inspection is that the Superintendent/Supervising Pharmacists were not obliged to maintain documentary evidence of the ongoing assessment of compliance with legislation and PSI guidance by the pharmacy. The Group also noted that although the PSI currently publishes an Inspector's Checklist for the current Regular/Systems inspections and that it appeared to be regularly used by the profession in preparation for an inspection, there is no obligation on Superintendent/Supervising Pharmacists to complete this checklist as part of any of the PSI processes. Furthermore, according to the feedback from the Authorised Officers, it appeared that compliance rates were higher in those pharmacies where there was evidence that the PSI Inspection checklist has been used.

On this basis, and having regard to the practices of other regulatory and inspection bodies, the Group acknowledged the important role of self-assessment in providing assurance of the ongoing internal review of the systems and risks in place in the pharmacy.

Recommendation 2

The Group recommends that the PSI should implement a system whereby pharmacists conduct regular detailed reviews of the practices and potential risks at the pharmacy to facilitate and encourage a culture of continuous improvement of pharmacy practice and ensure that the pharmacy is operating to the highest standards of patient safety at all times.

Role of Self-Assessment

The Group was of the view that in order to maximise the value of self-assessment in pharmacies in developing a culture of compliance and continuous improvement in the interest of patient safety, a self-assessment with a broader scope which provides for a more detailed reflection and analysis of the manner in which the pharmacy complies with all relevant pharmacy and medicines legislation, including the provisions of the Health (Pricing and Supply of Medical Goods) Act 2013 would be necessary. It also considered that the self-assessment should provide for the review of all of the practices and assessment of the potential risks at the pharmacy. The Group also agreed that the term self-audit was more appropriate to describe this type of exercise. To illustrate its vision, the Group gave some consideration as to a possible structure for such a self-audit which is built around assuring patient safety. This is set out in Appendix 15.

The Group also suggested that it would be important that such self-audits are conducted at least biannually (every six months) or as a response to a significant change to the operation of the pharmacy such as, change in staffing (increase or decrease), re-fit/renovation of the pharmacy, change in pharmacy activity (arising from a new prescriber in the area, change in patient population, introduction of a new service, seasonal variation, etc.). Notwithstanding this, in light of the significant impact that the change of a Superintendent or Supervising Pharmacist or events such as the relocation of the pharmacy might have on the operation of the pharmacy, the Group was of the view that such changes should trigger the completion of a new self-audit.

In recognition of the clinical and corporate structure of the pharmacy as provided for in the Pharmacy Act, the Group was of the view that the Supervising Pharmacist, as the person who is in whole time charge of the pharmacy, would be the most appropriate person to complete this type of exercise. Furthermore, the Group also suggested that the Superintendent Pharmacist as well as the pharmacy owner/representative of the pharmacy owner should also be involved in the self-audit process by reviewing/signing-off on the completed document.

In addition, the Group was of the view that it should be mandatory for both the Pharmacy Owner and the Superintendent Pharmacist to provide support and necessary resources to the Supervising Pharmacist to facilitate the completion of the self-audit. The Group also noted that 22 out of 26 respondents to the questionnaire issued to national and international regulatory and inspection bodies incorporated the self-assessment by regulated entities into their regulatory approach. Furthermore, 11 out of 22 regulators had a system of mandatory self-assessment which was reviewed during the course of the inspections it conducted. On this basis, the Group further agreed that completion of the type of self-audits it envisages should be mandatory. The Group further agreed that a statutory basis making it mandatory would be preferable and recognised that this may require an amendment to the current pharmacy legislation[16].

Recommendation 3

a) The Group recommends that the PSI develops a template to facilitate a detailed reflection and analysis of the manner in which the pharmacy complies with all relevant pharmacy and medicines legislation and should provide for the review of all of the practices and assessment of the potential risks at the pharmacy. This should be called the PSI Self-Audit.

b) The Group also recommends that it should be mandatory for all Supervising Pharmacists to compete self-audits of the pharmacy for which they are responsible at least biannually (every six months).

c) Furthermore, the Group recommends that Superintendent Pharmacists and Pharmacy Owners should be obliged to confirm to the PSI that such self-audits are being completed in this way.

Linking Self-Assessment and Inspection

The Group then considered if the process for mandatory self-audit could be linked to the inspection process. It noted that the current inspection checklists were being used by pharmacists to help them to prepare for an inspection. Furthermore, it noted that inspectors reported that in general standards of compliance were higher where there was evidence that these checklists were being used. Also, a number of respondents to Survey 1 expressed very positive comments in relation to the usefulness of inspection checklists in preparation for a PSI inspection. Therefore it appears that

[16] The Group was of the view that it was outside its area of competence to suggest which piece of legislation should be amended.

there is already an interest from the profession in assessing its own compliance with current legislative and best practice requirements.

The Group agreed that an inspection methodology could be developed whereby the Inspector could review and challenge the self-audit to verify that the observations and required actions cited by the Supervising Pharmacist were an accurate reflection of the practices and procedures in place in the pharmacy. On this basis, the Group envisaged a system of inspection which would combine documentary review, examination of the premises, and observation of the practices and patient interactions in the pharmacy.

The Group recognised that the quality of self-audits conducted by Supervising Pharmacists would be a significant factor which would influence the length of individual inspections conducted under the proposed model. Where self-audits are being conducted on a regular basis and reflect the practices at the pharmacy, the inspection process should be relatively straightforward for both the Inspector and the Supervising Pharmacist. In the event that the inspection identified issues relating to compliance and/or patient safety the process would be more complex.

In light of this vision for future inspections, the Group agreed that on the basis that the Supervising Pharmacist is the person who should be responsible for completing the self-audit, they should also be involved in the inspection. Noting that there is no provision in the legislation which obliges the Supervising Pharmacist to be present in the pharmacy on every single day that the pharmacy is open and operational, the Group considered the possibility of notifying the pharmacy in advance of the inspection to ensure that the Supervising Pharmacist is present on the day of the inspection. The Group also suggested that a notification period of 7 days would be necessary to give a fair opportunity to amend schedules and rotas to facilitate the presence of the Supervising Pharmacist and to allow time to arrange additional pharmacist cover for the duration of the inspection.

In considering this possibility, the Group noted the following:

- the response received from the Department of Health which includes the statement:
  "The department believe that the announced/unannounced nature of the inspection be at the discretion of the regulatory body"
- 12 out of the 23 national and international regulators provided notice to the inspected party for the purposes of meeting with key personnel
- the feedback provided by Inspectors which suggested that in cases where the Supervising Pharmacist was present for the inspection, it was generally more efficient.
- the responses from the Pharmacist Survey which indicated a preference by pharmacists to be notified in advance of an inspection. A significant number of comments were made (n=34) stating that inspections should be announced to ensure there is adequate staffing in the pharmacy.

Taking all of the above into consideration, the Group was of the view that there would be merit in providing notification by the PSI to pharmacies in advance of an inspection model based on the type of self-audit described above. However, the Group also agreed that the Supervising Pharmacist should play an active role in the inspection and should be available to the Inspector for the full duration of the inspection for the following (by way of example):

- Introduce the staff to the inspector.
- Provide an overview of the operation of the pharmacy.
- Give the inspector a tour of the pharmacy including all storage areas.
- Provide answers or further information to the Inspector.

The Group was of the view that it should be mandatory for the Supervising Pharmacist to be available to the Inspector and furthermore that the pharmacy owner should be obliged to ensure that there is additional professional cover in the pharmacy to relieve the Supervising Pharmacist of his/her pharmacy duties for the duration of the inspection and to enable him/her to participate fully in the inspection process. The Group further agreed that a statutory basis making it mandatory would be preferable and recognised that this may require an amendment to the current pharmacy legislation[17].

Recommendation 4

a) The Group recommends that a type of pharmacy inspection should be introduced which would also be conducted under Section 67 of the Pharmacy Act. The inspection should be based on the PSI inspector meeting with the Supervising Pharmacist at the start of the inspection and conducting a review of the self-audits which have been completed by the Supervising Pharmacist for the pharmacy. Through a combination of documentation review, examination of the premises, observation of the practices at the pharmacy, and asking questions the Inspector will establish that the pharmacy is operating in compliance with the legislation, PSI guidance and is providing a safe service to patients and the public by establishing the governance structure in the pharmacy, the manner in which all aspects of the pharmacy are operated and the manner in which risks are identified and managed in the pharmacy.

b) The Group recommends that this type of inspection should be called a "Pharmacy Governance and Practice Inspection".

c) The Group also recommends that the scope/content of a Pharmacy Governance and Practice Inspection should be appropriately flexible to ensure that the inspection process keeps pace with the expected continued evolution of the role of pharmacists and pharmacies in the Irish health system.

The Group also recognised the differences in the practice environment and patient needs in a hospital pharmacy which is registered as a retail pharmacy business compared to a community pharmacy practice. However, it also recognised that there are a number of the provisions relating to the obligations on the pharmacy, the pharmacy owner and the pharmacist in the legislation as well as in the PSI guidance and PSI Code of Conduct for Pharmacists which were equally relevant to both practice settings.

[17] The Group was of the view that it was outside its area of competence to suggest which piece of legislation should be amended.

Recommendation 5

The Group recommends that hospital pharmacies which are registered as Retail Pharmacy Businesses should also be subject to routine PSI inspections.

The Group was of the view that the report was a very important element of the inspection process and recommended that reports continue to be issued after the inspection in a similar manner to that currently in place as part of the Regular/Systems Inspection. The Group also acknowledged the importance of the report in assisting the PSI to build a risk profile on individual pharmacies. Therefore, it was of the view that when designing the reporting process, consideration be given to the manner in which data collected from the routine inspection process can be easily extracted for the purposes of aggregate publication of findings and relevant statistics on the PSI website, PSI Annual Report etc.

Recommendation 6

a) The Group recommends that the PSI should continue to issue a written report after each "Pharmacy Governance and Practice Inspection" to provide feedback on the findings from the inspection.

b) The Group also recommends that the PSI develops a process to extract key findings recorded in these reports for the purposes of publishing aggregate findings and relevant statistics on the PSI website, Annual Report etc. in the interests of transparency and learning.

A Proposed Model Based on Risk

Having regard to the concept of risk based regulation which is premised on targeting resources to areas of highest risk to patient safety, the Group agreed with the current policy to prioritise inspections on the basis of perceived risk to patient safety, arising from an assessment by the Head of the unit of the information available to the PSI.

Taking this into consideration, the Group agreed that the Pharmacy Governance and Practice Inspection would also facilitate the prioritisation of inspections on the basis of risk to patient safety. The Group also considered the intervals at which pharmacies should be inspected under this model and agreed that inspections should be conducted as frequently as necessary to provide the assurance necessary to the PSI that patients and the public are not placed at risk.

Arising from the completion of Cycle 1, the Group noted that there was more information available to the PSI on which to base future risk assessments. In addition, the Group also agreed that it would be appropriate to continue to schedule Pharmacy Governance and Practice Inspection of pharmacies with similar risk profiles on the basis of their geographical location (i.e. pharmacies in a particular region/along a particular route would be scheduled for inspection together) to maximise the efficient use of inspector time and resources.

Furthermore, the Group agreed that the Pharmacy Governance and Practice Inspection was fundamentally a risk-based model for the following reasons:

- It recognises the need to allocate increased inspector time to observing pharmacy practice activities (including pharmacist-patient interactions and the provision of safety information to patients) that can be very important in reducing risks for patients. This is afforded by the requirement for the Supervising Pharmacists to complete self-audits which can be efficiently reviewed by the Inspectors and which will enable additional time to be spent to inspecting practice issues during the inspection.
- It ensures that the appropriate pharmacy staff are present during all routine inspections, especially the Supervising Pharmacists. This helps achieve more risk-based inspections, as it allows the PSI Inspectors to spend the maximum amount of time inspecting the areas that may be of highest risk, without the problem that is sometimes encountered during unannounced inspections where the Supervising Pharmacist is not present and other pharmacy staff are not able to answer key questions or to provide the necessary information to the Inspectors in relation to risk issues.
- It continues to allow for unannounced inspections to occur, whenever the PSI is of the opinion that such inspections are necessary, on a risk-basis.

Recommendation 7

a) The Group recommends that the Pharmacy Governance and Practice Inspection should be conducted by the PSI at sufficiently regular intervals to provide the necessary assurances regarding each registered retail pharmacy business. The PSI should prioritise Pharmacy Governance and Practice Inspections on the basis of a risk assessment of the information available to it.

b) The Group recommends that the PSI should also continue to schedule Pharmacy Governance and Practice Inspections of pharmacies with similar risk profiles on the basis of their geographical location (i.e. pharmacies in a particular region/along a particular route would be scheduled for inspection together) to maximise the efficient use of inspector time and resources.

Overview of the proposed model

Appendix 16 includes a graphic that illustrates a summary of the responsibilities and activities for the main players in the proposed model namely the Supervising Pharmacist, Superintendent Pharmacists and Pharmacy Owners and PSI Inspectors.

Overall, the Group was of the view that the proposed model for future routine inspections would provide for a very robust, risk-based and flexible model of inspection. It would also provide substantial assurances to the PSI that the Supervising Pharmacist is discharging their function at the pharmacy on an ongoing basis in the interest of patient safety. The Group was also of the view that this model would ultimately result in the improved standards of practice in pharmacies.

However, in order to ensure that it conducted a balanced analysis of the Pharmacy Governance and Practice Inspection, the Group also considered the following potential challenges:

- The model will represent a significant change from current policy which is based on unannounced inspections which will require an investment of time and resources by the PSI to implement successfully.
- Superintendent, Supervising Pharmacists and pharmacy owners will have to adjust to a new type of routine inspection which the PSI will have to support though engagement and guidance.
- The PSI will have to design, pilot and implement a completely new type of inspection.
- It will take time for the Supervising Pharmacist to complete the type of self-audit as described in the model which may be perceived as an additional administrative burden on the pharmacy.

Recommendation 8

The Group recommends that the PSI should develop an implementation strategy to manage the challenges identified with the Pharmacy Governance and Practice Inspection.

5.3 Implementation Strategy for Pharmacy Governance and Practice Inspections

As part of its work, the Group considered an implementation strategy for the Pharmacy Governance and Practice Inspection. The Group was of the view that high quality communication and engagement with each of the key groups of pharmacy personnel would be very important in achieving successful roll-out of the model.

The Group also agreed that piloting the Pharmacy Governance and Practice Inspection in a sufficient number of pharmacies would be very important to test the newly designed inspection processes to ascertain that they are effective as well as to learn and gain feedback from both Inspectors and pharmacies before finalising the process for the full roll out stage.

Recommendation 9

The Group recommends that the implementation strategy for the Pharmacy Governance and Practice Inspection should take place in two stages:

- Stage 1: Design and Piloting
- Stage 2: Full Roll-out – to be commenced as soon as possible after Stage 1

The Group then gave consideration the tasks that the PSI should complete in Stage 1 – Design and Piloting. In addition, the Group was of the view that this Stage would ensure that Stage 2 – Full Roll Out would be as smooth as possible.

Recommendation 10

The Group recommends that Stage 1 include at least the following:

- Introduce the Pharmacy Governance and Practice Inspection to each of the key groups of personnel (Superintendent Pharmacists, Supervising Pharmacists, employee pharmacists, pharmacy owners, Pharmaceutical Assistants, various pharmacy and representative bodies etc.) as soon as possible utilising combination of different methods of communication and engagement including local and regional meetings, videos, podcasts, website updates, information documents etc.
- Design new inspection processes for piloting.
- Select the pharmacies to receive pilot inspections.
- Prepare guidance to support the proposed model including how to complete the self-audit and how to prepare for a new-type inspection.
- Train Inspectors in conducting the pilot inspections.
- Conduct a sufficient number of pilot inspections to elicit feedback to refine and further develop new inspection processes based on the proposed model (including reporting processes) and guidance based on the proposed model.
- Develop a framework to facilitate judgement by the Inspector during the inspection process.

The Group was of the view that once Stage 1 is complete, the PSI should progress to Stage 2 as soon as possible. As for Stage 1, the Group was of the view that high quality communication and engagement with each of the key groups of personnel identified above would be very important in achieving successful roll out of the Pharmacy Governance and Practice Inspection in Stage 2. The Group gave consideration to the target audience and content for communication in this stage.

Recommendation 11

a) The Group recommends that high quality communication and engagement to each of the key groups of personnel (Superintendent Pharmacists, Supervising Pharmacists, employee pharmacists, pharmacy owners, Pharmaceutical Assistants, various pharmacy and representative bodies) would be very important in achieving successful implementation of the Pharmacy Governance and Practice Inspection in Stage 2.

b) The Group recommends that a combination of different methods of engagement including local and regional meetings, videos, podcasts, website updates, information documents etc. should be employed by the PSI to ensure that pharmacists and pharmacy owners are afforded a full and fair opportunity to become informed of and comply with the expectation of the PSI in relation to the operation of the pharmacies for which they are responsible under the proposed model of inspection. In addition to this, it recommended the issuance of a complete set of clear, unambiguous and up-to-date guidance on legislative and best practice requirements for pharmacy in Ireland which would be reviewed and updated as necessary over the course of the roll out stage.

c) The Group also recommends that the PSI carefully monitors the roll out of Pharmacy Governance and Practice Inspection and provides a mechanism for inspectors and pharmacists to feedback to ensure maximum opportunity for sharing of information and learning from the new processes.

Having regard to the fact that to date hospital pharmacies have only been inspected as part of a registration process, it will be necessary to develop specific inspection processes and guidance to support and facilitate routine inspections of hospital pharmacies in the future.

Recommendation 12

The Group recommends that two separate, but parallel approaches to the roll out of Pharmacy Governance and Practice Inspections for both community and hospital practice settings.

Having regard to the number of registered retail pharmacy businesses in the State and having regards to the length of Cycle 1, the Group also gave consideration to the length of the next cycle of Pharmacy Governance and Practice Inspections.

Recommendation 13

The Group recommends that it would be a reasonable target for the PSI to conduct a Pharmacy Governance and Practice Inspection in every pharmacy in the State under the proposed model within 5 years of the commencement of the full roll-out (i.e. Stage 2) subject to certain factors such as the availability of PSI resources generally (specifically inspector resources).

Finally, the Group noted that unannounced activities have a very important role in the PSI's regulatory toolkit in assuring patient safety. The Group was of the view that the introduction of the Pharmacy Governance and Practice Inspection does not limit future inspection or investigation activities which may be conducted by the PSI under the authority of Section 67 of the Pharmacy Act.

Recommendation 14

The Group recommends that the PSI continues to conduct its other activities under Section 67 of the Pharmacy Act 2007 on an unannounced basis as such visits provide for a more accurate assessment and insight into the operation of a pharmacy and its compliance with pharmacy and medicines legislation on a day-to-day basis as experienced by patients.

Report of the Expert Group
on
A Strategic Review of the Current Policy for Routine Pharmacy Inspections

October 2014

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Appendix 1:

Terms of Reference for Project Expert Group

Terms of Reference for the Project Expert Group on Inspection Policy

1. Background

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies

The Pharmacy Act 2007 gives the PSI significant powers of inspection, investigation and enforcement. Authorised Officers in the Inspection and Enforcement Unit of the PSI conduct inspections of retail pharmacy businesses (RPBs) to assess compliance with the Act and with other pharmacy and medicines legislation, in the interests of patient safety and public protection.

By the end of 2014, Authorised Officers will have completed the first cycle of pharmacy inspections[1] of all RPBs. The aim of this cycle of inspections was to verify that each RPB is operating at a baseline standard of compliance with current medicines and pharmacy legislation and guidance.

The Council of the PSI is now committed to reviewing the current inspection policy and developing a new inspection policy for routine inspections[2] for the next cycle of routine pharmacy inspections. An independent Project Expert Group will be appointed by Council to undertake this work, hereinafter referred to as the Inspection Policy Project. The Expert Group will be supported by the Inspection and Enforcement Unit of the PSI and Ms Lucia Crimin has been assigned the role of Project Manager for the Inspection Policy Project.

2. Membership

An independent Project Expert Group will be appointed[3] comprising persons with expertise in *inter alia* regulation, inspection methodologies, risk management, policy development and the operation of pharmacies in both a community/retail and hospital environment to provide technical advice and assist in developing a new inspection policy for PSI. The Project Manager will be responsible for supporting the Expert Group.

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[1] Including registration related inspections, but not including for-cause inspections or investigations.

[2] For-cause inspections or investigations fall outside the scope of the Inspection Policy Project.

[3] Expressions of interest will be sought for the representative of public interest, two Community Pharmacists and one Hospital Pharmacist members of the Expert Group.

The members of the Expert Group are as follows:

- Person with experience of regulation or enforcement (Chairperson)
- Person with expertise in risk management
- Community pharmacist – Superintendent or Supervising Pharmacist
- Community pharmacist – Employee Pharmacist (not working as a Superintendent or Supervising Pharmacist)
- Hospital pharmacist – Superintendent Pharmacist
- Person with experience in inspection (other than pharmacy inspection)
- Representative of public interest
- Project Manager

3. Objectives

The objectives of the Expert Group include:

- Define the rationale and purpose of the routine pharmacy inspection;
- Examine current PSI inspection policy;
- Conduct research into national and international inspection models in healthcare and other relevant sectors;
- Consult with key national stakeholders;
- Prepare a report based on the findings containing a recommendation for a new inspection policy and a new inspection model for implementation by PSI.

Over the duration of the project, the Chairperson may determine if it is necessary for the Expert Group to undertake some additional tasks or provide some additional expertise on matters related to the scope of the project.

4. Corporate Governance

The Expert Group is obliged to conduct its activities within the Corporate Governance Framework and rules of the PSI.

5. Frequency of meetings

The Expert Group will meet as required as determined by the Chairperson.

6. Reporting arrangements

The Expert Group shall prepare a report based on its findings containing recommendations for a new inspection policy. On completion of this report, the Expert Group shall provide the report to the Registrar of the PSI who shall prepare a response from the executive of the PSI. The Expert Group shall also provide a copy of the report to the Inspection and Enforcement Committee (one of the six Advisory Committees of Council) at the same time.

The Registrar's response shall then be provided to the Inspection and Enforcement Committee (one of the six Advisory Committees of Council) for their consideration in conjunction with the Expert Group report. The Inspection and Enforcement Committee shall make a recommendation to Council on the basis of the report and the response from the Registrar.

The report of the Expert Group together with the Registrar's response and the recommendation from the Inspection and Enforcement Committee shall be provided to Council. Council shall take the final decision to adopt the new Inspection Policy.

The Inspection and Enforcement Unit shall design and implement the necessary inspection processes in accordance with the inspection policy as adopted by Council.

7. Termination of the Expert Group

The work of the Expert Group will conclude upon submission of the report to the Registrar, unless otherwise directed by the Inspection and Enforcement Committee.

Appendix 2:

Membership of the PSI Inspection Policy Project Expert Group

Membership of the PSI Inspection Policy Project Expert Group

Mr Noel Conroy (Chairperson)	**Person with experience of regulation or enforcement** Noel Conroy was the Garda Commissioner from July 2003 until he retired in November 2007. He joined the Garda Síochána in 1963 and has served at a senior level in a number of areas Gardaí. He is a graduate of the FBI Academy as well as FBI National Executive Institute. Noel has served on the PSI's Audit Committee from 2009 to 2013 and has also provided advice on training to the Inspection and Enforcement Unit.
Kevin O'Donnell	**Person with expertise in risk management** Kevin O'Donnell is currently Market Compliance Manager at the Irish Medicines Board (IMB). In this role he is responsible for a number of compliance-related and market-surveillance programmes, such as the quality defect and recall programme, the sampling and analysis programme and IMB's advertising compliance programme. Kevin is also a Senior Inspector at the IMB and performs Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good Clinical Practice (GCP)(bioequivalence) inspections. Kevin joined the IMB in 2001, having worked in the pharmaceutical industry both in Ireland and in the United States before then. He obtained PhD in the field of Quality Risk Management from the Dublin Institute of Technology in 2008. He also holds an MSc in Pharmaceutical Quality Assurance. Kevin has led the IMB's work over the last number of years in relation to developing risk-based inspection strategies and related tools; he was also rapporteur for the development of a PIC/S tool for risk-based GMP inspection planning that was officially adopted in January 2012. (PIC/S is the Pharmaceutical Inspection Cooperation Scheme and is an organisation comprising of over 40 Inspectorates worldwide that runs inspector training and other activities.) He is currently involved in co-chairing a Heads of Medicines Agencies working group that is tasked with developing a risk-based approach for the surveillance of medicinal products in the EU.

Niall Byrne	**Person with experience in inspection (other than pharmacy inspection)** Niall Byrne is the Deputy Director of Regulation in HIQA where he is responsible for the regulation of Adult Social Care. Currently, this involves registering, inspecting and enforcing requirements across 600 residential centres for older and dependent people and approximately 1,200 residential settings for adults with disabilities, which, in total, cater for over 38,000 long-term residents. Currently, there are 93 posts assigned to this function of which 59 are inspection posts assigned to 9 geographic inspection teams each led by an area manager. Approximately 2,400 inspections of all types are expected to be delivered in 2014. Before joining HIQA in early 2009, Niall spent almost 10 years working as Head of HR and Service Quality for a voluntary organisation providing residential care and support to adults with disabilities. Prior to that, he was a civil servant for 18 years with the Revenue Commissioners and the, then, Department of Social Welfare where he worked in a number of operational and policy posts. He holds a BA degree in Public Administration from the IPA and a Higher Diploma in Quality in Healthcare from RCSI together with a Masters Degree in Business Studies from UCD Graduate School of Business and an MA in Human Development from DCU.
Ms Marese Damery	**Patient/Public Representative** Marese has a background in nursing and is the Health Check Co-ordinator at the Irish Heart Foundation. Marese holds a Bachelor of Nursing Science from Trinity College Dublin.
Ms Caroline McGrath MPSI	**Employee Pharmacist Nominee – Chain/Group of Pharmacies** Caroline McGrath is the Clinical Governance Pharmacist in Boots Ireland. Caroline has 11 and a half years of experience in various roles including support pharmacist, supervising pharmacist, pharmacy manager and area manager in a number of Boots Pharmacies in Ireland. Caroline holds a BSc(Pharm) from Trinity College, an MSc (Healthcare Management) (Community Pharmacy) from RCSI and is currently undertaking a Bachelor of Laws (LLB (Hons)) in Irish Law at Griffith College Dublin.

Mr Michael Tierney MPSI	**Superintendent/Supervising Pharmacist– Independent Pharmacy** Michael Tierney is the Superintendent and Supervising Pharmacist at Tierney's Pharmacy, Rathdrum, Co Wicklow. Michael has 34 years' experience as a registered pharmacist. Michael holds a Bachelor of Pharmaceutical Science from UCD.
Ms Veronica Treacy MPSI	**Superintendent Pharmacist Nominee – Hospital Pharmacy** Veronica Treacy is the Superintendent Pharmacist in St James's Hospital Dublin. She has over 35 years' experience as a registered pharmacist and has held the role of Superintendent Pharmacist for the last 6 years. Veronica holds a Bachelor of Pharmaceutical Science from UCD, a Masters in Business Administration (MBA) from University of Luton and a Certificate of Clinical Pharmacy from the London School of Pharmacy.
Lucia Crimin MPSI (Project Manager)	**Pharmacist, Inspection & Enforcement Unit, PSI** Since joining PSI in January 2010, Lucia has worked in the Inspection and Enforcement Unit as a Pharmacy Inspector and was also Acting Head of the Registration and Qualification Recognition Unit (Maternity Cover). In October 2012, Lucia was seconded to the Department of Health to work on the health agenda for the Irish Presidency of Ireland to the EU. In this work, Lucia was involved in the negotiation of new European legislation on Medical Devices, Clinical Trials and Drug Pre-cursors in Brussels. She was also involved in developing national policy and legislation in the area of pharmacy, medicines and cosmetics. Lucia returned to PSI in April 2014. Lucia holds a BSc(Pharm) from Trinity College Dublin and a Masters in Business Administration (MBA) from UCD.

Appendix 3:

PSI Inspection and Enforcement Policy Document

INSPECTION & ENFORCEMENT POLICY DOCUMENT

1.0 INTRODUCTION

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland.

The PSI acts to protect the health and safety of the public by regulating the pharmacy profession and the operation of pharmacies in the state. The PSI aims to ensure that pharmacy services are delivered in a competent professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice.

2.0 PURPOSE OF THIS DOCUMENT

Under the Pharmacy Act 2007, the PSI is responsible, inter alia, for:

- Regulating the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public;
- Supervising compliance with the Act and the instruments made under it.

The PSI has a dedicated Inspection and Enforcement Unit to deal with inspection and investigation activity. The purpose of this document is to inform affected parties about the PSI's approach to inspection and investigation activity. The document is informed by our core remit of protecting patient safety and public health.

3.0 INSPECTION FUNCTION

The PSI inspects retail pharmacy businesses to assess compliance with the Pharmacy Act 2007 and with other pharmacy and medicines legislation and guidelines.

The purpose of the inspection function is to promote good and safe pharmacy practice within retail pharmacy businesses. The primary objective of the PSI through its inspection remit is to promote and ensure high standards of voluntary compliance with legislative requirements, guidelines, best practice requirements and the Code of Conduct for Pharmacists and to improve the delivery of pharmacy services and the standard of operation of retail pharmacy businesses.

The principle under which inspections will be undertaken is one that is based on perceived risk. It is not overly invasive but is constantly vigilant.

3.1 Nature and Types of Inspection Activity

The PSI carries out two main types of inspections:

- **Inspections of New Pharmacy Openings/Registrations**

  The PSI registers retail pharmacy businesses in accordance with the Pharmacy Act and the regulations and rules made thereunder. The PSI may carry out an inspection of a proposed retail pharmacy premises as part of the registration process. This inspection assesses compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008 and PSI Guidelines.

  The PSI has published a checklist to assist pharmacy owners and pharmacists to prepare for new opening inspections and to inform them what to expect during an inspection. The checklist is available at www.thepsi.ie

  Where the PSI conducts an inspection on foot of an application to register[1] a new retail pharmacy business, the PSI will give notice of the inspection in writing to the applicant.[2] Once the inspection is completed, the Authorised Officer (inspector) generates a report which is provided to the applicant. The report will identify required actions which must be undertaken by the applicant in order to comply with legislative requirements and/or relevant guidelines. The PSI seeks written confirmation from the applicant that required actions identified in the report have been remedied before the registration application is progressed to its conclusion.

  Inspections of New Pharmacy Openings are carried out as and when they are required. Retail pharmacy businesses normally undergo an inspection as part of their registration process.

- **Regular Pharmacy Inspections**

  Regular Pharmacy Inspections can be notified or un-notified. The decision to notify these inspections is a matter for the discretion of the PSI.

  The PSI has published a checklist and a podcast to assist pharmacy owners and pharmacists to prepare for these inspections and to inform them what to expect during an inspection. The checklist and podcast are available at www.thepsi.ie

  Once the inspection is completed, the PSI will issue the pharmacy owner and/or the superintendent pharmacist as the case may be with an Authorised Officer's report. The report will identify non-compliances observed during the inspection and required actions which must be undertaken in order to comply with legislative requirements and/or relevant guidelines. The PSI will seek written confirmation from the pharmacy owner and/or the superintendent pharmacist within a specified timeline that the required actions identified in the report have been remedied.

  The PSI may carry out random follow up inspections to check that the remedial actions confirmed in writing have been carried out.

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[1] Section 19 of the Pharmacy Act 2007 provides that in any case where the Council considers it appropriate, it may cause an authorised officer to inspect the premises of a retail pharmacy business in respect of which an application for registration or continued registration has been made to ascertain if they comply with any regulations made by the Minister under section 18.

[2] Rule 5 (2)(c) of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses)(Registration)Rules 2008.

In circumstances where serious and/or recurrent breaches of legislation, the Code of Conduct for Pharmacists and PSI Guidelines are identified, the incidences of non-compliance will be considered for sanction on a case by case basis by the Registrar of the PSI in accordance with the provisions of the Pharmacy Act. (This will be addressed in detail in Section 4.2 below).

The PSI is committed to overseeing the completion of the first full cycle of Regular Pharmacy Inspections by the end of 2014. This objective constitutes the number one priority for the Inspection and Enforcement Unit. The nature and frequency of inspections is agreed on an annual basis.

The findings from the first cycle of inspections will assist the PSI to:

- Identify baseline compliance in connection with the operation of retail pharmacy businesses;

- Identify non-compliance trends and/or areas for improvement and to keep pharmacy owners and pharmacists informed of any practice or safety concerns observed.

- Develop a risk assessment methodology in order to ensure more targeted intervention for high risk inspected parties going forward. This will avoid over inspection of those pharmacies which present little or no risk to the public and allow the PSI to concentrate its resources on inspecting those pharmacies which pose the highest risk to patient safety and public protection.

The PSI also carries out joint inspections with other statutory bodies. The PSI engages with organizations such as the Irish Medicines Board (IMB), An Garda Siochana, The Health Service Executive (HSE) and the Department of Agriculture, Food and the Marine.

Specialist Surveyors
The PSI engages specialist surveyors to carry out mystery shopper activity and to conduct test purchases in retail pharmacy businesses.

4.0 ENFORCEMENT FUNCTION

The overall goal of the PSI is to ensure patient safety and public protection through proportionate regulation. The purpose of PSI's enforcement activity is to:

- To detect breaches of pharmacy and medicines legislation, guidelines and the Code of Conduct for Pharmacists or to detect professional misconduct.

- To ensure that appropriate action is taken against those who breach the law and/or who fail in their legal or professional responsibilities.

- Prevent and deter non-compliance with pharmacy and medicines legislation, guidelines and the Code of Conduct for Pharmacists and to prevent and deter professional misconduct.

- To enforce compliance through the use of regulatory sanctions, as appropriate.

The PSI is committed to ensuring transparency, fairness, proportionality, and consistency in pursuit of compliance and the use of enforcement action. Authorised Officers of the PSI have signed a Code of Conduct for Authorised Officers and are committed to behaving with integrity, impartiality and transparency in their dealings with pharmacy owners , pharmacists and members of the public.

4.1 Nature and Types of Investigations

The PSI carries out investigations[3] under the Pharmacy Act 2007. Investigations typically involve an inspection or series of inspections, as well as speaking to the pharmacy owner, pharmacist or other staff at the pharmacy or a member of the public. Records and product is often reviewed and/or detained in evidence as part of the investigation process.

Investigations are carried out to ascertain, inter alia, whether:

- Offences have been committed under the Pharmacy Act 2007, the regulations made under the Pharmacy Act and Irish Medicines Board legislation.
- Any breach of the PSI Code of Conduct for Pharmacists has been committed.
- Professional misconduct has been committed by either retail pharmacy businesses or pharmacists.

Investigations are also carried out for obtaining information or evidence about the above matters.

PSI Investigation activity is risk based and intelligence led. Investigations are carried out as a result of non-compliances identified in the inspection process or using intelligence (from the PSI internally, other agencies or members of the public) which has been risk assessed. Investigations are never carried out without a reason. This ensures the most effective use of resources allowing the PSI to focus on those areas which pose the greatest risk.

Investigation activities are frequently conducted in conjunction with other agencies. The PSI has carried out investigations with the Irish Medicines Board (IMB), The Health Service Executive (HSE) and the Department of Agriculture, Food and the Marine.

Once an investigation is concluded an Authorised Officer's report is completed. A copy of the report may be furnished to the party (pharmacist/pharmacy owner) under investigation or inspection. The pharmacist/pharmacy owner is invited to submit their comments on the contents of the report. The report and submissions (if provided) are considered by the Registrar of the PSI.

4.2 Nature and Type of Enforcement Actions

Following consideration of an Authorised Officers Report[4], the PSI may:

(a) Take no action;

(b) Commence disciplinary proceedings against pharmacists and/or pharmacies;
This involves making a complaint against pharmacists and/or retail pharmacy businesses.

(c) Refer matters to other agencies in the event that it appears that the person to whom the report relates is guilty of an offence
In cases where an offence appears to have has been committed which is outside the scope of pharmacy or medicines legislation, the PSI may refer the file to the relevant agency.

(d) Take such other action as it considers appropriate in the circumstances.

[3] Investigations are carried out under part 7 of the Pharmacy Act 2007.
[4] An Authorised Officers report is considered by the Council of the PSI or the Registrar of the PSI as the case may be under section 71 of Pharmacy Act 2007.

This has included the following:

- Issuing warning letters in the context of minor non-compliances
- Seeking undertakings from pharmacists and/or pharmacies in various terms
- Initiate district court proceedings under the Pharmacy Act 2007 or the Irish Medicines Board Act 1995 (as amended) in the name of the Council of the PSI. District court proceedings are taken in the cases of serious or recurrent non-compliance breaches. The PSI publishes the outcomes of the prosecutions taken on the PSI website.

5.0 MEMORANDA OF UNDERSTANING

The PSI is committed to partnering with other relevant enforcement agencies of the State and to develop Memoranda of Understanding (MOU) with such agencies. The PSI has Memoranda of Understanding with An Garda Siochana, HIQA, the Irish Medicines Board (IMB) and the Medical Council.

The PSI will seek to develop MOUs with other regulatory and law enforcement partners, aimed at promoting strong inter agency co-operation around joint operation and facilitating two-way sharing of information and intelligence.

6.0 OPERATIONAL MATTERS

The PSI is governed by a 21 member Council, with a non-pharmacist majority, appointed by the Minister for Health and Children. The Council established an Inspection and Enforcement Committee to advise it in relation to the performance of its functions in the area of inspection and enforcement. This Committee is made up of both Council members and co-opted members who have a special knowledge and experience relating to the purpose of the committee. The Inspection and Enforcement Committee report regularly to the Council of the PSI on its business.

The Inspection and Enforcement Unit is made up of the Head of Inspection and Enforcement Unit, a number of Authorised Officers (inspectors) and inspection and registration executives.

The PSI is committed to ensuring that its inspection and enforcement activity is adequately supported with resources, skills, procedures and technology to enable it to discharge its functions in the area of inspection and enforcement.

Detailed end to end processes and procedures are in place to cover all aspects of inspection, investigation and enforcement to ensure a robust, compliant and consistent approach. Inspection and investigation activities are conducted in line with these processes.

The PSI monitors its achievements in the area of inspection and enforcement through its business planning (yearly service plan) and reporting.

Appendix 4:

Checklist for a Pharmacy Inspection by the Pharmaceutical Society of Ireland

Checklist for a Pharmacy Inspection by The Pharmaceutical Society of Ireland

The following is a non-exhaustive list of what may be reviewed by an Authorised Officer of the PSI during a Pharmacy Inspection. This checklist is intended as a self-assessment tool to assist you in preparing for an inspection. In addition you should be familiar with pharmacy and medicines legislation, accessible via the PSI website www.thePSI.ie and www.irishstatutebook.ie and PSI guidelines accessible via the PSI website and the links below.

1.0	**Registration Certificates**	**Yes**	**No**
1.1	Is the current certificate of registration for the pharmacy available at the pharmacy and is it displayed such that it is legible from the public pharmacy area?		
1.2	Is the current certificate of the supervising pharmacist available at the pharmacy and is it displayed such that it is legible from the public pharmacy area?		
2.0	**Storage of Medicinal Products**	**Yes**	**No**
2.1	Are all prescription-only medicines, including veterinary prescription-only medicines (if applicable) stored in the dispensary?		
2.2	Are all codeine containing non-prescription medicines and other CD5 controlled drugs stored in the dispensary?		
2.3	Are all pharmacy only medicines stored behind the medicines counter?		
2.4	Are all other non-prescription medicines stored in an area of the pharmacy under the control of the pharmacist?		
2.5	Does the pharmacy have a pharmaceutical grade fridge?		
2.6	Is the fridge clean and is food stored in a separate fridge?		
2.7	Are all medicines stored in the fridge in good condition?		
2.8	Is the fridge of an adequate capacity to permit the orderly storage of medicines?		
2.9	Is the fridge serviced annually?		
2.10	Is the maximum/minimum fridge temperature monitored, recorded and reviewed on a daily basis as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business?		

2.11	Are all medicines stored in the pharmacy in date and is there an active documented expiry date management system in place? The expiry dates of medicines may be checked.		
2.12	Is the maximum/minimum temperature in the dispensary and any additional storage areas monitored, recorded and reviewed on a daily basis as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business?		
2.13	Are medicinal products only removed from their primary packaging in exceptional circumstances? If they have been removed are they labelled with all information required as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business? Have all stability implications been considered?		
	PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business		
3.0	**Policies and Standard Operating Procedures**	**Yes**	**No**
3.1	Has the pharmacy a full suite of written procedures for all processes carried out in the pharmacy?		
	At a minimum, the following procedures should be in place:		
	a) Dispensing: This includes the entire process from the receipt of the prescription, through therapeutic review to the transfer of the medicine to the patient and patient counselling. Dispensing procedures should address the dispensing of different types of medicines, including high-risk medicines (Methotrexate etc.), High-tech medicines, Controlled drugs etc.		
	b) Sourcing of medicines		
	c) Storage of Medicines		
	d) Expiry Date checking		
	e) Sale and supply of non-prescription medicinal products. These procedures should address the general supply of non-prescription medicines and the supply of specific products (Norlevo, Alli, Domperidone, Curanail etc.)		
	f) Sale and supply of non-prescription codeine containing medicines		
	g) Management of controlled drugs (including storage and record keeping)		
	h) Disposal of medicines and destruction of controlled drugs		
	i) Management of additional services provided, including (as applicable): Point of care testing services, seasonal influenza vaccination services, monitored dosage systems, veterinary services, methadone services etc.		

	j) Error and incident management. There should be error records in place and corrective actions should be recorded.		
	k) Locum Procedure		
	l) Housekeeping and cleanliness of the dispensary (including equipment), public pharmacy area and all other areas of the pharmacy. There should be a cleaning schedule or sign off sheet in place.		
	m) Use of the patient consultation area. This should address directing patients to the area and supervision of the pharmacy while a pharmacist is engaged in a consultation.		
	n) Pest control policy		
	o) Policy on use of child resistant containers		
	p) Management of emergency situations, e.g. loss of electricity/ power		
	q) Keyholding Policy for the premises and CD Safe and security procedures. Is access to the pharmacy and medicines only permitted in the presence of the pharmacist?		
3.2	Have all policies and procedures been approved by the superintendent and supervising pharmacist?		
3.3	Is there an implementation date for all procedures?		
3.4	Is there a review date for all procedures and is documentation relating to previous reviews available?		
3.5	Are dated policy and procedure training records available for all staff for all relevant procedures?		
4.0	**Duty Register**	**Yes**	**No**
4.1	Does the pharmacy have a duty register for the current year?		
4.2	Is there a pharmacist supervising the pharmacy for all hours of opening and is this recorded in the duty register?		
4.3	Is the duty log being maintained correctly? Are all entries maintained contemporaneously, are they signed by the pharmacist and do they include the pharmacist's arrival and departure times?		
4.4	Does the supervising pharmacist work in the pharmacy for a significant proportion of the opening hours?		
4.5	Is the duty register reviewed regularly to ensure all details are correct?		

4.6	Pharmaceutical Assistant (if applicable). If a pharmaceutical assistant is employed at the pharmacy and providing temporary cover in the absence of the pharmacist, are they operating in accordance with the Code of Practice Governing their Temporary Absence?		
5.0	**Prescription Register/Daily Audit/ Daily Dispensing Report**	**Yes**	**No**
5.1	Is the prescription register/ daily dispensing report printed on a daily basis (within 24 hours)?		
5.2	Is the prescription register/ daily dispensing report dated and signed by the pharmacist?		
5.3	Is the prescription register/ dispensing report completed in the correct format in accordance with the requirements of regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)? Are emergency supplies recorded and if at the request of a patient is the reason for the emergency supply recorded?		
5.4	Is the prescription register/ daily dispensing reports for the previous two years available for review at the premises?		
5.5	Are all prescriptions for the previous two years available for review at the premises?		
6.0	**Controlled Drugs (CD) Register**	**Yes**	**No**
6.1	Does the pharmacy have a Controlled Drugs register?		
6.2	Is the CD register completed in accordance with legislation and instructions, i.e. is a dedicated page provided for each product, are all required details entered, are the details entered in chronological order within 24 hours of supply and are errors corrected by marginal/ footnotes etc?		
6.3	Is there evidence of the pharmacist routinely reviewing and checking stock balances?		
6.4	Are all CD registers for the last two years available for review?		
6.5	Where controlled drugs have been removed from the active balance and destroyed is there documentation relating to the witnessed destruction of controlled drugs available for review?		
7.0	**Controlled Drug Inventory**	**Yes**	**No**
7.1	Do the quantities of CDs recorded in the register match the quantities located in the CD safe?		

8.0	Controlled Drug Safe	Yes	No
8.1	Is there a lockable safe/ cabinet for the storage of medicines (schedule 2 & 3 controlled drugs) in place in the dispensary?		
8.2	Is the CD safe secured (bolted to a solid wall/ floor) in accordance with regulations?		
8.3	Has the CD safe been certified by the Gardaí and is the certificate available for review at the pharmacy? Note: This certificate is valid for two years from the date of issue.		
8.4	Does the CD safe have sufficient capacity to permit the orderly storage of all schedule 2 & 3 controlled drugs?		
8.5	Are all CD2 and CD3 controlled drugs stored in the CD safe? Is the CD safe reserved solely for the storage of medicines?		
8.6	Are expired/ patient returned controlled drugs stored in a designated part of the CD safe and appropriately labelled?		
10.0	**Extemporaneous Medicinal Products (if applicable)- on foot of prescriptions**	**Yes**	**No**
10.1	Are there procedures in place for preparing extemporaneous products?		
10.2	Are detailed records of products prepared maintained?		
10.3	Is all required equipment available in the pharmacy?		
10.4	Is all equipment clean and appropriately calibrated?		
Note: Extemporaneous preparation is only permissible on foot of prescriptions in limited circumstances			
11.0	**Prescriptions**	**Yes**	**No**
A number of controlled drug and medicinal product prescriptions will be requested and reviewed during the course of the inspection.			
11.1	**Controlled drugs (CD2) Prescriptions:**		
	Are the original prescriptions available for review?		
	Are they valid and in date (dispensed within 14 days of the date on the prescription and not dispensed prior to the date on the prescription)?		
	Do they meet the handwriting requirements for controlled drugs?		
	Have they been entered correctly into the CD register and prescription register?		
	Have they been endorsed with the date of dispensing and the word 'dispensed'/ quantity dispensed?		

11.2	**Medicinal Product Prescriptions:**		
	Are the original prescriptions available for review?		
	Are they valid and in date (dispensed within 6 months of the date on the prescription)?		
	Are they correctly written?		
	Have they been entered correctly into the prescription register?		
	Have they been endorsed with the date of dispensing and the word 'dispensed'/ quantity dispensed?		
12.0	**Premises**	**Yes**	**No**
12.1	Is the premises self-contained?		
12.2	Has the PSI/Garda Security Assessment been completed and are there adequate security arrangements in place, e.g. alarm, shutters, CCTV, panic buttons, as applicable? Have any/all recommendations made by the crime prevention officer been implemented?		
12.3	Is the external and internal premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard?		
12.4	Are all storage areas in the premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard?		
12.5	Are all entrances to the premises well maintained, clear and accessible?		
12.6	Is the trading name of the pharmacy displayed at all entrances to the premises?		
12.7	**Dispensary**-Is the dispensary area easily identifiable by signage?		
12.8	Does the layout enable the pharmacist to both maintain patient confidentiality and exercise supervision of the sale and supply of medicinal products in the dispensary, at the medicines counter and while in the patient consultation area?		
12.9	Is a dispensing bench with a smooth impervious & washable surface and adequate space for expected volume of activity in place?		
12.10	Is there a dedicated dispensary sink with access to hot and cold (potable) water?		
12.11	Are dedicated areas for preparing Extemporaneous Products/ Monitored Dosage Systems in place (if applicable)?		
12.12	Is adequate lighting/ ventilation provided in the dispensary?		
12.13	**Medicines Counter**-Does the location of the medicines counter restrict access to pharmacy only medicinal products?		

12.14	Is access to the dispensary/ non-prescription medicines area and all areas where medicines or confidential records are stored restricted to authorised personnel?		
12.15	Is a suitable waiting area provided for patients?		
12.16	**Patient Consultation Area** -Does the premises have a separate, designated, conveniently located private patient consultation area, which is directly accessible from the public area of the pharmacy?		
12.17	Does the patient consultation area comply with the PSI's Guidelines on Patient Consultation Areas , in terms of size, wheelchair accessibility, signage, provision of a table/ worktop & three chairs? Note: The area can't be the only access route to another area of the pharmacy.		
12.18	If the seasonal influenza vaccination service is provided in the pharmacy does the patient consultation area meet the requirements of the PSI's Guidelines?		
12.19	Is there a clean and well maintained staff toilet with wash hand basin and a staff break area provided at the premises?		
12.20	Are all areas of the premises where medicines or records are stored included in the floor plan of the registered premises submitted to the PSI?		
12.21	Is housekeeping in all areas of the pharmacy maintained at an acceptable standard?		
13.0	**Residential Care Settings (if applicable)**		
13.1	Are there procedures in place which address the management of the supply of medication to patients in residential care homes? The procedures should address the entire process, including the receipt of prescriptions, the delivery of medicines, the management of controlled drugs, medicine therapy reviews and patient counselling etc. Practice Notice: Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes. Letters to Superintendents on Residential Care Homes: Letter 1, Letter 2		
13.2	Are records of the following available for review for all patients in residential care settings:		
	Patient consent?		
	Medicines delivery?		
	Pharmacist visits?		
	Patient counselling?		
	Interdisciplinary medicine therapy review?		

14.0	Veterinary Medicinal Products (if applicable)	Yes	No
14.1	Are veterinary medicinal products stored in a designated area(s) of the pharmacy?		
14.2	Are prescription medicines, prescription only exempt medicines, pharmacy only medicines, licenced merchant medicines, companion animal remedies and veterinary medicines requiring refrigeration stored appropriately? Note: A separate pharmaceutical grade fridge is required for veterinary medicines.		
14.2	Does the pharmacy have a veterinary register?		
14.3	Are records of all incoming and outgoing veterinary medicines (VPOM, VPOM(E), PS and LM) recorded in the veterinary register in accordance with legislative requirements?		
14.4	**Veterinary Prescriptions :**		
	Are they available?		
	Are they in date (dispensed within one year of the date on the prescription)?		
	Are they correctly written?		
	Have they been entered correctly into the veterinary register?		
	Have they been endorsed with the date of dispensing, the word 'dispensed' and signed by the pharmacist?		
14.5	Are all records (register and prescriptions) for the last five years available for review at the premises?		
15.0	**Miscellaneous**	**Yes**	**No**
15.1	Does the pharmacy have all required equipment?		
	General Equipment (telephone, fax, label printer etc.).		
	Computer, with pharmacy email and internet access.		
	Electronic dispensing system and drug interaction software		
	Dispensing Equipment (tablet counter, dispensing containers (tablet vials, bottles, ointment jars, plastic bags/ cardboard cartons), child resistant containers (CRCs), disposable plastic cups etc.		
	Extemporaneous equipment (graduated cylinders, ointment slab, electronic NAWI compliant balance (accurately measures 100mg to 200g), certified metric weights, mortars and pestles weighing boats, spatulas & stirrers etc.)		
15.2	Does the pharmacy have appropriate reference books?		
	Martindale or other complete drug reference (current or most recent edition)		

	Current BNF & Current BNF for children (or other appropriate current children's reference)		
	Current Shockley's (or other detailed drug interaction reference) and drug interaction software		
	Access to relevant current PSI guidelines, pharmacy and medicines legislation and SmPCs of medicinal products authorised in Ireland (hard copy or internet access)		
	Additional references if additional services are provided, e.g. veterinary reference, if providing veterinary services		
15.3	Does the pharmacy have a medicinal product waste bin and a designated storage area for the bin?		
	Is all waste and patient returned medication stored in a designated area of the pharmacy segregated from active stock pending timely processing?		
	Is evidence of waste collections by an authorised waste management company available?		
15.4	Does the pharmacy have a methylated spirits register and license (if applicable) and is there a designated area for the storage of methylated sprits?		
15.5	Does the pharmacy have a poisons register (if applicable) and are poisons stored in an appropriate designated area of the pharmacy?		
15.6	Does the pharmacy have a shredder for confidential paper waste?		
15.7	Is the pharmacy registered with the Data Protection Commissioner and is a policy which covers all electronic and manual records in place?		
15.8	Does the pharmacy have a confidentiality policy in place for all staff?		

Appendix 5:

Findings from 2013 Regular/Systems Inspections

Inspection Findings 2013

The PSI carries out inspections of pharmacies under Section 67 of the Pharmacy Act 2007 to ensure, in the public interest, the safe supply of medicines and the promotion of the highest standards in pharmacy practice.

In 2013, 388 regular/systems inspections were carried out by the PSI. Systems inspections are unannounced inspections of pharmacies by Authorised Officers (Inspectors) of the PSI. These inspections examine the way in which medicines, including prescription only medicines and controlled drugs are supplied from the pharmacy to ensure a legitimate and safe basis for their supply. These inspections also review premises, workflow and the conditions existing for the storage and preparation of medicines, as well as the governance and quality systems of a pharmacy.

An overview of the findings and key statistics for those inspections in 2013 are provided below. These are based on an analysis of the findings from 387 inspections, which were carried out in 2013. Relevant resources are also provided to assist pharmacists, pharmacy owners and pharmacy staff in meeting the standards of compliance expected under the Pharmacy Act 2007, including inspection checklists that are available both for regular/systems inspections and for new pharmacy openings.
These findings were made available in two parts through the PSI newsletter in June and August 2014.

PART ONE

Part one of this overview provides the key statistics regarding the supply of medicines to patients in nursing homes and/or residential care settings, quality management systems, and pharmacy premises and medicines storage.

1. Supply of Medicines to Patients in Nursing Homes/Residential Care Settings[1]

The sale and supply of medicines to patients in nursing homes or residential care settings are examined to verify that medicines are safely supplied in accordance with original prescriptions, which were reviewed by the pharmacist prior to supply. This review looks at procedures and records governing the supply of medicines, the use of prescriptions, patient counselling and medication use reviews to ensure that patients in nursing homes or residential care facilities receive the same level of professional care as those patients who present in person at a pharmacy.

Item checked during inspection	**% of pharmacies meeting compliance standard**s
Use of Original Prescriptions Pharmacists confirmed that original prescriptions are always present and reviewed in the pharmacy before medicines are	71%

dispensed to patients in Nursing Homes/Residential Care Settings	
Procedures Written procedures are in place to govern the supply of medicines to patients in Nursing Homes/Residential Care Settings	61%
Medicines Use Reviews Records show that medicines reviews are carried out	53%
Delivery Records Delivery records were available for review at the pharmacy for supplies to patients in Nursing Homes/Residential Care Settings	57%

Useful resources:

- Revised guidance for supply to nursing homes/residential care settings (February 2014)
- Medicinal Products (Prescription and Control of Supply Regulations) 2003 (as amended)
- Regulation of Retail Pharmacy Businesses Regulations 2008

2. Quality Management Systems

The quality management system is the overall system in place at the pharmacy to ensure that the pharmacy operates in a manner which is safe for patients and the public and is in accordance with legislation and best practice.

Standard Operating Procedures (SOPs) are a key part of the quality management system at the pharmacy. SOPs are documents which describe each process in the pharmacy in detail. Superintendent and Supervising Pharmacists should approve each of the SOPs for a pharmacy, ensure that all relevant staff are trained on SOPs relevant to their work and also that the SOPs are reviewed periodically to make sure they are up to date with best practice. The quality management system should also address how the pharmacy identifies and minimises risk through the reporting of errors and incidents, and the implementation of corrective actions. It is important that the quality management system is documented in order to demonstrate how the pharmacy operates in compliance with the law and best practice.

In conducting their review of the quality management system at the pharmacy, inspectors will ask to see a number of documents including SOPs, error and incident management systems and pharmacist staffing records which together demonstrate the quality management system in process.

Item checked during inspection	**% of pharmacies meeting compliance standards**
Evidence of Training in Pharmacy SOPs Records show that pharmacy staff were trained in the pharmacy's SOPs	60%
Error/incident logs Records show that error/incident logs were being	62%

maintained at the pharmacy	
Record of Pharmacist on Duty The duty register was properly maintained in respect of the particular dates checked.	78%

Useful resources:

- Inspectors' Advice on Standard Operating Procedures (SOPs) is available on the PSI website (Dec 2013)
- Regulation of Retail Pharmacy Businesses Regulations 2008

3. Pharmacy Premises and Medicines Storage

Pharmacy premises are reviewed to verify that there is a safe and effective working environment for the storage, preparation and sale and supply of medicines. The premises are checked to ensure that they are in good repair, clean and orderly. The public pharmacy area, the dispensary, storerooms and the staff sanitary facilities are reviewed as part of this check. Storage arrangements for fridge medicines, dispensary medicines and expiry date checking systems are reviewed to make sure that medicines are stored in accordance with the requirements of their marketing authorisations. The patient consultation area is also reviewed to ensure that it is a private, designated area, easily accessible to patients so that they may discuss their medicines therapy in confidence.

Item checked during inspection	**% of pharmacies meeting compliance standards**
Patient Consultation Area A Patient consultation area was in place	95%
Dispensary Dispensary was clean and/or well maintained	80%
Storerooms Storerooms were clean and/or well maintained	64%
Bathrooms Staff bathrooms were clean and/or well maintained	77%
Pharmaceutical grade fridge Pharmaceutical grade fridges are in place for the storage of medicines in the pharmacy	85%
The medicines fridge is clean	92%
Maximum/minimum temperature records monitored and recorded on a daily basis in the: - Pharmacy fridge - Dispensary - Storage Areas	66% 50% 54%

Useful resources:

- Inspectors' Advice on Storage Conditions available on the PSI website (Feb 2014).
- PSI Guidelines on Sourcing, Storage and Disposal of medicinal products within a retail pharmacy business
- PSI Guidelines on Patient Consultation Areas

PART TWO

Part two of this overview provides the key statistics[2] regarding the supply of prescription only medicines and the management of controlled drugs in pharmacies.

4. The Supply of Prescription Only Medicines

Prescriptions are examined to ensure there is a legitimate and valid basis for the safe supply of prescription only medicines (POM), including controlled drugs (CD). PSI Inspectors normally select four supplies and ask to see the prescriptions used to authorise these supplies during a routine systems inspection. A total of **1548** supplies were selected for review. 50% of these supplies related to the supply of controlled drugs.

In certain emergency circumstances, prescription only medicines can be supplied at the request of a patient and/or a prescriber subject to specific safeguards being adhered to. It should be noted that controlled drugs can never be supplied without a prescription or using the 'emergency supply' exemption referred to in legislation. 96 of the 1548 (6.2%) supplies checked were 'emergency supplies'.

Of the items checked during inspection:

- 92% (1424 of 1548) of the prescriptions checked were in date and valid
- 85% (1315 of 1548) of the prescriptions reviewed were properly written
  15% (232 of 1548) of the prescriptions checked were not properly written. The majority of these prescriptions related to the supply of schedule 2 controlled drugs. In particular, it was noted that:
  • The quantity of medicines/dosage units to be supplied was not written in both words and figures, as required by legislation.
  • The name and address of the patient was not handwritten on the prescription, as required by legislation.
- 26% (25 of 96) of the 'emergency supplies' reviewed were carried out in accordance with legislative requirements
  74% (71 of 96) of the 'emergency supplies' reviewed were not carried out in accordance with the necessary legislative requirements. A breakdown of these figures shows that:
  • In 49.3% (47 of 96) of these cases[3] controlled drugs were supplied.
  • In 38% (37 of 96) of these cases the quantity of medicines supplied to the patient exceeded the permitted quantity allowed in respect of an emergency supply carried out at the request of a patient.
  • In 11.3% (11 of 96) of cases where the supply was requested by a prescriber, the original prescription was not supplied to the pharmacy within 72 hours after the supply, as required.
  • Other 1.4% (1 of 96).

Useful resources:

- The Medicinal Products (Prescription and Control of Supply Regulations) 2003 (as amended)
- Inspectors' Advice on Emergency Supply available on the PSI website (May 2012)
- Inspectors' Advice on Controlled Drug (CD) Compliance available on the PSI website (February 2012)

5. Management of Controlled Drugs

The controlled drugs register is reviewed to ensure that all receipts and supplies of schedule 2 controlled drugs are legitimately accounted for. Stock checks are carried out during the inspection to verify that the quantity of stock specified in the controlled drugs register corresponds with the physical quantity of the controlled drug in the safe. PSI Inspectors review the balances for three controlled drugs preparations during each inspection.
PSI Inspectors also check to make sure that schedule 2 and 3 controlled drugs are securely stored in a locked controlled drugs safe.

Item checked during inspection	% of pharmacies meeting compliance standards
Controlled Drugs Register Running stock balances were recorded in the Controlled Drugs Register	90%
Controlled drug stock checks were correct i.e. the physical quantity of the controlled drug counted matched the balance in the controlled drugs register	91%
In 6% (23 of 387) of cases omissions were identified in the Controlled Drugs Register. In these cases supplies to patients were not recorded in the register and/or controlled drugs received from wholesalers were not recorded in the register.	
Controlled Drugs Safe All controlled drugs (schedule 2 and/or schedule 3) were stored in the controlled drugs safe	92%

Useful resources:

- Misuse of Drugs Regulations 1988 (as amended)
- Misuse of Drugs (Safe Custody) Regulations 1982 (as amended)
- Regulation of Retail Pharmacy Businesses Regulations 2008
- Inspectors' Advice on Controlled Drug (CD) Compliance available on the PSI website (February 2012)

[1] 115 of the 387 Retail Pharmacy Businesses inspected supplied patients in Nursing Homes/Residential Care Settings.
[2] These findings relate to the specific aspects of the pharmacy's systems assessed on the date of the inspection.
[3] 89% of the supplies relate to the supply of schedule 3 or schedule 4 controlled drugs.

Appendix 6:

Surveys for Pharmacists, Pharmaceutical Assistants and Pharmacy Owners

PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Survey 1

To be completed by persons who have experienced a PSI inspection

1. How would you rate your knowledge of the PSI's Inspection and Enforcement function?
   (1 being no knowledge and 5 being excellent knowledge)

2. What type of inspection did you experience? (please tick)
   a. New Opening Inspection □
   b. Regular/Systems Pharmacy Inspection □
   c. Both □

3. What was your area of pharmacy practice at the time of the inspection? (please tick)
   a. Community Pharmacy (independent or group less than 5 pharmacies) □
   b. Community Pharmacy (group more than 5 pharmacies) □
   c. Hospital Pharmacy □

4. What was your role in the Pharmacy at the time of your inspection? (please tick)
   a. Superintendent Pharmacist □
   b. Supervising Pharmacist □
   c. Employee Pharmacist (in regular employment at the pharmacy) □
   d. Locum Pharmacist (providing occasional/once-off professional cover at the pharmacy) □
   e. Pharmaceutical Assistant □
   f. Pharmacy Owner/Director (pharmacist) □
   g. Pharmacy Owner/Director (non-pharmacist) □

5. Was the inspection process for the ***New Opening Pharmacy Inspection*** what you expected?
   Y □ N □
   Please comment.

6. Based on your experience, please provide your feedback on the current ***New Opening Pharmacy Inspection*** process.

7. Do you feel that you were adequately prepared for the inspection?

   Y ☐ N ☐

   Please comment.

8. Was the inspection process for the ***Regular/Systems Pharmacy Inspection*** what you expected?
   Y □ N □
   Please comment.

9. Based on your experience, please provide your feedback on the current ***Regular/Systems Pharmacy Inspection*** process.

10. Do you feel that you were adequately prepared for the inspection?

    Y □ N □

    Please comment.

11. Which of the following PSI resources do you use to help you to prepare for an inspection?

    a. PSI Website □
    b. PSI Newsletter Articles □
    c. Self-assessment checklist □
    d. Other (please describe) □

12. What other resources should the PSI provide to help you to prepare for an inspection? Please describe.

13. Please insert any additional comments below. For example any changes which were made to the operation of the pharmacy other than those corrective actions set out in the inspection report.

Appendix 7:

Analysis of Surveys of Pharmacists, Pharmaceutical Assistants and Pharmacy Owners

PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Survey 2

To be completed by persons who have ***not*** experienced a PSI inspection

1. How would you rate your knowledge of the PSI's Inspection and Enforcement function? (no knowledge to excellent knowledge)

2. What is your area of pharmacy practice? (please tick)
    a. Community Pharmacy (independent or group less than 5 pharmacies) □
    b. Community Pharmacy (group more than 5 pharmacies) □
    c. Hospital Pharmacy □
    d. Academic □
    e. Industry □
    f. Not practicing □
    g. Other (please describe) □

3. What is your current role? (please tick)
    a. Superintendent Pharmacist □
    b. Supervising Pharmacist □
    c. Employee Pharmacist (providing regular professional cover at a pharmacy) □
    d. Locum Pharmacist (providing occasional/once-off professional cover at a pharmacy) □
    e. Pharmaceutical Assistant □
    f. Pharmacy Owner/Director (non-pharmacist) □
    g. Pharmacist not working in a community/hospital pharmacy □
    h. Not practicing □

4. Which of the following PSI resources do think help pharmacists and pharmacy owners to understand the current PSI Inspection Process?
    a. PSI Website □
    b. PSI Newsletter Articles □
    c. Self-assessment checklist □
    d. Other (please describe) □

5. Please insert any additional comments below.

Appendix 7:

Analysis of Surveys of Pharmacists, Pharmaceutical Assistants and Pharmacy Owners

Analysis of the Survey of Pharmacists, Pharmacy Owners and Pharmaceutical Assistants on the Current PSI Inspection Policy

Two surveys were prepared on the current PSI inspection process – one for those persons who have experienced a PSI inspection and a second for those persons who have not experienced a PSI inspection or are not likely to be inspected (by virtue of their area of practice).

Electronic versions of the two surveys were issued on Friday 25 July by email to all registered pharmaceutical assistants as well as all registered pharmacists and pharmacy owners. Hard copy versions of the two surveys on current PSI inspection processes were issued on 30 July to those pharmacists, pharmacy owners and pharmaceutical assistants who, according to the PSI Registers, do not have an email address.

The survey closed on Monday 11 August. In total 598 respondents participated in the two surveys (585 completed the electronic version of the survey and 17 completed the survey in hard copy).

Survey 1: Persons who have experienced a PSI Regular/Systems Inspection

Survey 1 included questions on both the current PSI Regular/Systems Inspection and the current PSI New Opening Inspection processes.

The following table presents the **roles and areas of practice** of the respondents* (n=206):

Area of Practice at the time of the inspection	Community Pharmacy (independent or group less than 5 pharmacies)	74.75%
	Community Pharmacy (group more than 5 pharmacies)	23.78%
	Hospital	1.45%
Role in the Pharmacy at the time of the inspection	Superintendent Pharmacist	53.39%
	Supervising Pharmacist	54.85%
	Employee Pharmacist (in regular employment at the pharmacy)	21.84%
	Locum pharmacist (providing occasional/once-off professional cover at the pharmacy	2.91%
	Pharmaceutical Assistant	7.76%
	Pharmacy Owner/Director (pharmacist)	22.33%
	Pharmacy Owner/Director (non-pharmacist)	0.0%

*respondent may have selected more than one option

Respondents were also asked to rate their knowledge of the **PSI's Inspection and Enforcement function.** The following table presents the results (n=206):

No knowledge	1.46%
Some knowledge	15.4%
Good knowledge	43.69%
Very good knowledge	31.55%
Excellent knowledge	8.25%

A. Regular/Systems Inspection

The following table presents the results of Survey 1 in relation to Regular/Systems Inspections:

Had experience of a Regular/Systems Inspection (n=206)	72.82%			
Had experience of both a New Opening Inspection and a Regular/Systems Inspection (n=206)	17.48%			
Regular/Systems Inspection was as expected (n=188)	Yes	72.41%	No	26.59%
Adequately Prepared for the inspection (n=188)	Yes	66.49%	No	33.51%

Survey 1 also included a section in which respondents were asked to provide their comments of their experience of a Regular/Systems Inspection. In total 213 respondents made 532 individual comments in response to the following questions:

- Was the inspection process for the Regular/Systems Inspection what you expected? (Question 8)
- Based on your experience, please provide your feedback on the current Regular/Systems Inspection process. (Question 9)
- Do you feel that you were adequately prepared for the inspection? (Question 10)
- Any other comments (Question 13)

The following table presents the categories under which respondents commented in relation to the current Regular/Systems Inspection Process:

Positive Comments on Regular/Systems Inspections	
General support for the concept of an inspection	14
Inspection process was thorough/fair	32
Inspection process was straightforward	8
The inspection was not as intimidating/stressful as expected	4
PSI/IPU checklists/self-audits were helpful in preparing for the inspection	24
The Inspection did not interfere with the operation of the pharmacy	9
Inspection was a positive experience	10
Positive comment on the conduct of the inspector	34
Feedback from inspector was good/helpful	8
Learned from inspection/raised standards in the pharmacy as a result	13
Inspection report was useful leverage to implement certain changes in the pharmacy	4

Negative Comments on Regular/Systems Inspections	
Inspection process was too detailed/focused on regulations	26

Inspection process focused on finding fault/no acknowledgement of good practice	17
Inspection process should be about providing advice and not punishing/adversarial	16
Inspection should be outcomes focussed and look at all aspects of the pharmacy (including patient care)	12
Inspection process should include a self-assessment by the pharmacy	2
Difficult to conduct the business of the pharmacy during the inspection	46
Inspection was a negative experience	11
Negative comment about the conduct of the inspector	13
Inconsistencies between inspectors/inspections	5
Inspectors don't understand how a pharmacy operates/Inspector was not a pharmacist	7
Feedback from inspector was poor/not provided	4
Inspection process included some unexpected/inappropriate elements e.g. painting, toilets etc.	6
Negative comment about the Inspection Report (not easy to read/not reflective of inspection feedback/delay in issuing the report)	6
Inspection took place at a busy time in the pharmacy (e.g. Friday of Bank Holiday or Frist of the Month)	9
Inspection was more/less thorough than expected	4
Comments on Announcing Regular/Systems Inspections	
Inspections should be announced in advance (no reason given)	12
Inspections should be announced in advance to prevent risk to patient/mistake being made	7
Inspections should be announced in advance to ensure Supervising Pharmacist is present	6
Inspections should be announced in advance to ensure adequate staffing in the pharmacy for the inspection	34
Inspections should be announced in advance to ensure pharmacy is prepared/everything is in order	11
Inspections should be announced in advance to make them less stressful for the pharmacy	9
Inspections should only be unannounced in the case of an investigation/on foot of specific information	7
Announced was helpful to be prepared	2

NOTE: The figures set out above <u>are not cumulative</u> and it is not possible to reconcile them with the total number of responses.

B. New Opening Inspection

The following table presents the results of Survey 1 in relation to New Opening Inspections:

Had experience of a New Opening Inspection (n=206)	9.7%			
Had experience of both a New Opening Inspection and a Regular/Systems Inspection (n=206)	17.48%			
New Opening Inspection was as expected (n= 64)	Yes	74.5%	No	25.45%
Adequately Prepared for the inspection (n=64)	Yes	81.81%	No	18.18%

Survey 1 also included a section in which respondents were asked to provide their comments of their experience of a New Opening Inspection. In total 61 respondents made 116 individual comments in response to the following questions:

- Was the inspection process for the New Opening Pharmacy Inspection what you expected? (Question 5)
- Based on your experience, please provide your feedback on the current New Opening Pharmacy Inspection process. (Question 6)
- Do you feel that you were adequately prepared for the inspection? (Question 7)

The following table presents the categories under which respondents commented in relation to the current New Opening Inspection Process:

Positive Comments on New Opening Inspections	
Inspection process was straightforward/thorough process	21
Good information provided in advance	13
Positive comment about the conduct of the inspector	10
Inspection was a positive experience	5
Positive comment on the announced nature of New Opening Inspections	3
Negative Comments on New Opening Inspections	
Inspection process included unexpected/inappropriate elements e.g. standard of painting	5
Need more information in advance	6
Inspection for transfer of sole trader to limited company is not fair/registration process is too costly	2
Inconsistencies between inspectors	3
Negative comment about the conduct of the inspector	4
Inspection was a negative experience	3
Timelines for corrective actions too short	2

NOTE: The figures set out above <u>are not cumulative</u> and it is not possible to reconcile them with the total number of responses.

Question 11 asked respondents which **<u>PSI resources</u>** they use to **<u>prepare for an inspection</u>**. The following table presents the results (n=206 from Question 11):

PSI Website	61.65%
PSI Newsletter Articles	35.44%
Self-Assessment Checklists	75.24%
Other	32.52%

A total of 66 comments were received under the heading “other”. The following table presents the categories under which respondents commented:

IPU website/Self Audit	43 comments
Internal Company Checklist	3 comments
Advice from colleagues/word of mouth	5 comments

NOTE: The figures set out above are not cumulative and it is not possible to reconcile them with the total number of responses.

Question 12 asked respondents to provide details of **other resources which should be provided by PSI to help prepare for an inspection**. The following table presents the categories under which respondents commented (n=182):

Publish recent findings from inspections	34
Guidance/templates for SOPs	10
Guidance on the size of the Patient Consultation Area	3
Discussion forum between pharmacists and inspectors/query section on the website	2
Announce inspections in advance	36
PSI website/checklist is adequate	20
Suggestions to use podcasts/videos	4
Detailed Inspection Checklist/Guidelines	38
Road shows/meetings with Inspectors	13
Pharmacists to submit a Self-Assessment to PSI	3
Provide for “mock inspections”/”request an inspection”	2

NOTE: The figures set out above are not cumulative and it is not possible to reconcile them with the total number of responses

Survey 2: Persons who have not experienced a PSI inspection

The following table presents the **roles and areas of practice** of the respondents* (n=162):

Area of Practice at the time of the inspection	Community Pharmacy (independent or group less than 5 pharmacies)	51.23%
	Community Pharmacy (group more than 5 pharmacies)	26.54%
	Hospital	17.9%
	Academic	4.32%
	Industry	4.32%
	Not practicing	0.62%
	Other	4.94%
Role in the Pharmacy at the time of the inspection	Superintendent Pharmacist	23.46%
	Supervising Pharmacist	32.72%
	Employee Pharmacist (in regular employment at the pharmacy)	30.25%
	Locum pharmacist (providing occasional/once-off professional cover at the pharmacy	14.2%
	Pharmaceutical Assistant	8.64%
	Pharmacy Owner/Director (pharmacist)	6.79%
	Pharmacy Owner/Director (non-pharmacist)	0
	Pharmacist not working in a community/hospital pharmacy	6.17%
	Not practicing	1.85%

*respondent may have selected more than one option

Respondents were also asked to rate their knowledge of the **PSI's Inspection and Enforcement function.** The following table presents the results (n=162):

No knowledge	3.08%
Some knowledge	38.27%
Good knowledge	34.57%
Very good knowledge	17.9%
Excellent knowledge	5.56%

Question 4 of Survey 2 asked respondents were asked which **PSI resources** they thought help pharmacists and pharmacy owners to **understand the current PSI Inspection Process**. The following table presents the results (n=162):

PSI Website	62.34%
PSI Newsletter Articles	44.44%
Self-Assessment Checklists	75.31%
Other	8.64%

A total of 12 comments were received under the heading "other". The following table presents the categories under which respondents commented:

IPU website/information	10
Advance notice of inspection	1
CPD on Risk Assessment	1
Link to the Statute Book on the PSI Website	1
Word of Mouth	1

Question 5 of Survey 2 asked respondents to provide their comments on the **current PSI inspection process**. The following table presents the categories under which respondents commented (n=54):

Inspections should be announced in advance (no reason given)	4
Inspections should be announced in advance to ensure adequate staffing in the pharmacy for the inspection	7
Inspections should be announced in advance to ensure pharmacy is prepared/everything is in order	4
Inspections should be announced in advance to make them less stressful for the pharmacy	2
Inspections should only be unannounced in the case of an investigation/on foot of specific information	2
Inspection process should be different for community and hospital pharmacies/need guidance for inspection of hospital pharmacies	7
Regular feedback on inspection findings	5
PSI/IPU checklists/self-audits helpful in preparing	2
Inspection should be about providing advice/not punishing/adversarial	3

NOTE: The figures set out above are not cumulative and it is not possible to reconcile them with the total number of responses

Appendix 8:

Questionnaire for PSI Authorised Officers

PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Questionnaire for PSI Authorised Officers

Current PSI Regular/Systems Inspection Process

1. Approximately how many regular/systems inspections have you conducted?
2. On average, how long does it take you to complete a regular/systems inspection?
3. What is the average amount of time you engage with the pharmacist over the course of the inspection?
4. What factors affect your ability to interact with the pharmacist during the inspection?
5. What makes the process easier for you when you are conducting the inspection?
6. In general, how familiar are pharmacists with the inspection process? Do pharmacists/owners refer to the PSI website, Newsletter (Inspectors' advice) etc?
7. Is there evidence the pharmacists/owners are using the inspection checklists/conducting self-assessments in preparation for the inspection? Based on your experience, what is the impact of this on the inspection process?

8. Based on your experience, what changes in findings have you noticed over the last number of years?
9. What sort of feedback do you usually get at the end of the inspection?
10. What are the common questions asked during/after the inspection?
11. Please provide any additional comments on the current PSI Regular/Systems Inspection Process.

Appendix 9:

List of Key National Stakeholders Contacted

Lsit of Key National Stakeholders Contacted

National Stakeholders:

- Dr Ambrose McLoughlin & Ms Pamela Carter, DoH
- Mr Tony O'Brien HSE
- Mr Darragh O'Loughlin IPU
- Ms Deirdre Lynch, HPAI
- Mr Stan O'Neill, PIER

Patient Representative Organisations:

- Mr. Robin Webster, Age Action Ireland
- Mr. Gerry Martin, Alzheimer Society of Ireland
- Ms. Sharon Cosgrove, Asthma Society of Ireland
- Mr. Dominic Layden, Aware
- Ms Mags Mullarney, move4parkinsons
- Ms Eibhlin Mulroe, IPPOSI - Irish Platform for Patients' Organisations , Science and Industry
- Ms Sheila O'Connor, Patient Focus
- Mr. Keith Adams, Parkinsons Association of Ireland
- Mr. Patrick Little, Migraine Association
- Mr. Stephen McMahon, Irish Patients Association
- Mr. John McCormack, Irish Cancer Society
- Ms.Gina Plunkett, Irish Chronic Pain Association
- Mr. John Lindsay, Irish Chronic Pain Association
- Mr. Barry Dempsey, Irish Heart Foundation
- Mr. Kieran O'Leary, Diabetes Federation of Ireland
- Mr. John Dolan, Disability Federation of Ireland
- Mr. Philip Watt, Cystic Fibrosis Association of Ireland

Appendix 10:

Letter to Key National Stakeholders

Private and Confidential
[insert name and address]

30th July 2014

RE: Review of the current Pharmaceutical Society of Ireland pharmacy inspection policy

Dear *[insert name],*

I am writing to you in relation to a review of the current policy on the inspection of pharmacies which was commenced recently by the Council of the Pharmaceutical Society of Ireland (PSI). The PSI is the independent statutory regulator of pharmacists and pharmacies in Ireland and works to protect the health and safety of the public. As part of its function as the regulator, the PSI is empowered under the Pharmacy Act 2007 to conduct inspections of pharmacies for the purposes of assessing their compliance with national pharmacy and medicines legislation.

By the end of 2014, the PSI will have completed the first cycle of pharmacy inspections. In order to form the basis for the policy for the next cycle of inspections commencing in 2015, the PSI established a dedicated Project Team to conduct a review of the current inspection policy and make recommendations for a new policy. To assist with this work, a group of national experts in the areas of regulation, inspection methodologies, risk management, policy development and the operation of pharmacies in both a community/retail and hospital environment was appointed by the Council of the PSI.

As part of this review, the views of your organisation on the current inspection policy are now invited. For your convenience, I enclose a copy of the current PSI Inspection and Enforcement Policy document (which includes the current inspection policy). For further information on the PSI's inspection function, please visit the PSI website.

We would be grateful to receive any comments and observations that you may wish to make not later than 15 August 2014.

Your assistance in this matter would be greatly appreciated.

Yours sincerely,

Lucia Crimin
Project Manager
Inspection Policy Project
The Pharmaceutical Society of Ireland

Appendix 11:

List of National and International Organisations Contacted

List of National and International Organisations Contacted

National Healthcare Inspectorates	**National Non-Healthcare Inspectorates**

• Health Information and Quality Authority (HIQA)
• Pre Hospital Emergency Care Council (PHECC)
• Health Products Regulatory Authority (HPRA)
• Health Service Executive (HSE)
  – Environmental Health Officers
  – Pharmacy Inspectors
• Mental Health Commission
• Veterinary Council
• Department of Agriculture
 	
Irish Regulators with no inspection function
• Medical Council
• Dental Council
• Nursing and Midwifery Board of Ireland
• CORU – Health and Social Care Professionals Regulator
	• Food Safety Authority of Ireland
	• Radiological Protection Institute of Ireland
	• National Employment Rights Authority (NERA)
	• Central Bank of Ireland
	• Department of Social Protection
	• Office of the Revenue Commissioners
	• Environmental Protection Agency
	• Health & Safety Authority
	• An Garda Siochána
	• Commission for Aviation Regulation Ireland
	• Department of Education and Skills
	• Law Society of Ireland

International Pharmacy	**International Non-pharmacy**
• General Pharmaceutical Council (GPhC) • Pharmaceutical Society of Northern Ireland (PSNI) • Pharmacy Council of Australia • Pharmacy Council of New Zealand • College of Pharmacy Ontario, Canada • College of Pharmacy Alberta, Canada • Relevant Authorities in 26[1] EU Member States[2]	• Professional Standards Authority (UK) (oversees 9 statutory healthcare regulators in UK)

[1] Exception of UK (as GPhC and PSNI were contacted directly) and Ireland.

[2] The Health Attachés in the Permanent Representation Offices of each EU Member State in Brussles were contacted and asked to forward the questionnaire to the appropriate authority/agency with responsibility for the regulation of pharmacy in their Member State.

Appendix 12:

List of Respondents to Questionnaire Issued to National and International Organisations

List of Respondents to Questionnaire Issued to National and International Organisations

July 2014

National Healthcare Regulators	**International Pharmacy Regulators**
Health Information and Quality Authority (HIQA)	Pharmaceutical Services, Ministry of Health, Cyprus
Pre Hospital Emergency Care Council (PHECC)	Medicines Authority, Malta
Health Products Regulatory Authority (HPRA)	The Finnish Medicines Agency (Fimea)
The Veterinary Council of Ireland	The Pharmaceutical Society of Northern Ireland*
Health Service Executive (HSE) - Health and Wellbeing Division - Environmental Health Service	The State Institute for Drug Control, Czech Republic
Health Service Executive (HSE) – Corporate Pharmaceutical Unit	The State Medicines Control Agency, Lithuania
Department of Agriculture, Food & Marine	Pharmacy Registration Board of Western Australia
	General Pharmaceutical Council of Great Britain
National Non-healthcare Regulators	Alberta College of Pharmacists, Canada
Commission Aviation Regulation (CAR)	Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI)
Central Bank of Ireland	
Department of Education	
Food Safety Authority of Ireland (FSAI)	
Garda Professional Standards Unit (GPSU)	
National Employment Rights Agency (NERA)	
Revenue	
National healthcare Regulators with no inspection function	
Medical Council of Ireland	
CORU- The Health and Social Care Professionals Council	
Nursing and Midwifery Board of Ireland	

Appendix 13:

Questionnaire for Regulatory Bodies:

Regulatory and Inspection Policy

PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Questionnaire for Regulatory Bodies

-Regulatory and Inspection Policy-

Questionnaire for Regulatory Bodies

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of pharmacists and pharmacies in Ireland, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public

The PSI regulates the professional practice of approximately 5,200 pharmacists, and 1,800 pharmacies in Ireland. As part of its function as the pharmacy regulator, the PSI conducts inspections of pharmacies in both hospital and community settings. The PSI carries out two main types of inspections in accordance with the Pharmacy Act 2007:

- Inspections of new pharmacy openings conducted as part of the application process for registration of a new pharmacy (under Section 19 of the Pharmacy Act 2007), and
- Inspections of registered pharmacies (under Section 67 of the Pharmacy Act 2007).

Currently it is PSI inspection policy that the inspected party is only notified in advance of a new-opening inspection; routine inspections are carried out on an unannounced basis.

By the end of this year, the PSI will have conducted the first cycle of pharmacy inspections whereby at least one inspection (of either type) will have been conducted in every pharmacy in the State.

In anticipation of the completion of this first cycle of inspections, the PSI recently commenced a review of the current pharmacy inspection policy. As part of the work of this project, we are researching how other national and international pharmacy, healthcare and other regulatory bodies operate.

To assist us with this work, we invite you to complete the following Questionnaire with as much detail as possible. We kindly ask that you return the completed survey (in Word® format) to lucia.crimin@thePSI.ie before close of business on Friday 25 July 2014.

Lucia Crimin
The Pharmaceutical Society of Ireland
The Pharmacy Regulator
18-20 Fenian Street
Dublin 2
Ireland
www.thePSI.ie

Section A: About your organisation
1. Name of the organisation.
2. Who/what do you regulate?
3. What is the legislative authority under which you operate?
4. How many years is the organisation in operation?
5. Please describe how your organisation regulates. What is the Regulatory Policy/Strategy in operation?
6. What arrangements are in place for the oversight of the activities of the organisation i.e. does the organisation report to another body?
7. What methodologies does your organisation use to review its effectiveness as a regulator?
8. Has your organisation ever implemented a change in the regulatory policy? Please describe the manner in which the organisation managed the change. What was the basis for the change? Was the change successful?

Section B: About your inspection policy
1. Does the organisation have an inspection function?
2. Is there a fee for inspections? If so, how is the fee levied?
3. How many inspections are conducted on average per year?
4. How many inspectors are in the organisation?
5. What experience and qualifications do the inspectors have?
6. How often are inspections conducted? Please describe the methodologies used to select individual entities for inspection?
7. What, if any, notification is provided to the inspected parties in advance of the inspection?
8. Why are inspected parties notified?

9. What type of inspections do you carry out? ***Please select all relevant options.***

- Registration related (conducted as part of a process to licence or register an entity) □
- Compliance related (conducted to assess compliance of an entity with relevant legislation or other guidelines) □
- Other inspection types. (Please describe below). □

10. Please provide a brief description of the inspection process for each inspection type making reference to the following:

- Scope and purpose of the inspection (what is assessed during the inspection);
- How the inspection is conducted (inspection methodology);
- The average duration of the inspection.

11. What is the role of self-inspections/self-audits in your inspection policy? How does your organisation co-ordinate and review such self-inspections/self-audits?

12. Is a written report issued to the inspected party after the inspection? Please outline the structure/content of this report and if applicable please indicate the manner in which the inspected party responds to the report.

13. Are individual inspection reports published? Where are they published? At what stage in the inspection process are they published? How long are they published for?

14. Please provide a brief description of the actions which may be taken by the organisation after the report has been issued to the inspected party?

15. What implications might there be for an inspected party following an inspection?

16. Can your close or suspend the operation of the inspected party on the basis of an inspection? Please give a brief description of this process.

17. Are follow-up inspections carried out? Please give a brief description of the circumstances in which a follow-up inspection would be carried out.

18. Please insert any additional comments below. In particular, we would like you to describe what you have found to work well for your organisation in conducting inspections.

Section C: Contact Information

1. Questionnaire completed by:

2. Your Position in the organisation:

3. Contact details (phone and email):

Appendix 14:

Summary of Responses to the Questionnaire issued to National and International Pharmacy and Non-Pharmacy Bodies

Summary of responses to the questionnaire issued to national and international pharmacy and non-pharmacy bodies

On 11 July 2014, a questionnaire was issued to approximately 60 national and international regulatory bodies engaged in the regulation of both pharmacy and non-pharmacy activities.

Overview of all Responses Received

Status and Function of Regulatory Activity (n=26)

- 26/26 operate on a **statutory basis**
- 21/26 have a **defined inspection function**
    - 2/26 inspection function not defined but is performed
    - 3/26 no inspection function

Selection for Inspection (n=23)

- 16/23 conduct inspections at defined intervals
- 16/23 use risk based approach
- 3/23 random selection approach
- 1/23 carry out random re-inspections
- 7/23 conduct targeted inspections (trigger/complaint)
- 4/23 conduct inspections of new entities

Announced/unannounced Inspection types (n=23)

- 12/23 conduct a mixture of announced and unannounced inspections
- 6/23 conduct announced inspections only
- 4/23 conduct unannounced inspections only
- 1/23 conduct announced inspections in conjunction with unannounced spot checks of records/documentation

Reasons given for announcing inspections (n=23)

- 1/23 announces to provide notice to residents and relatives etc.
- 12/23 announce to ensure key personnel are available during the inspection
- 8/23 announce to ensure that required information and files are made available for the inspection
- 5/23 announce to promote, ensure compliance with standards
- 1/23 announce as it is a legislative requirement to notify
- 1/23 announce where re-inspection is required
- 1/23 announce for pre-registration purposes

Self-Inspection for Inspected Parties (n=22)

- 3/22 self-inspection information can be used during inspection, but is not mandatory
- 11/22 self-inspection is mandatory, reviewed during inspection (as part of quality management system)
- 1/22 legislative requirement to conduct self-inspection (does not impact on inspection conclusion)
- 7/22 self-inspection not used
- 1/22 statutory self-declaration of self-inspection as part of annual renewal

Inspection Process (n=22)

- 8/22 Different inspection processes used depending on area to be inspected
- 14/22 One inspection process for all entities

Inspection Methodologies (n=22)

- 17/22 assessment of systems and records associated with the activities conducted by the entity
- 2/22 "walk-through" of the premises
- 10/22 Meetings/interviews with personnel
- 3/22 Observation of practice
- 4/22 use a checklist/inspection template
- 2/22 provide advice to inspected party on site

Reporting (n=22)

- 2/22 no report issued
- 20/22 report issued
- 2/22 reports are peer reviewed before issuance
- 12/22 inspected parties given a timeframe within which they have to respond

Publishing of Reports (n=22)

- 5/22 publish reports
- 17/22 do not publish reports
- 4/22 publish inspection summary data

Follow up Inspections (n=22)

- 21/22 conduct follow up inspections
- 1/22 do not conduct follow up inspections

NOTE: The figures set out above <u>are not cumulative</u> and it is not possible to reconcile them with the total number of responses.

National Health-Care Inspectorates	
Respondents (n=6)	**HIQA** **HPRA** **PHECC** **The Veterinary Council of Ireland** **HSE - Health and Wellbeing Division - Environmental Health Service** **Department of Agriculture, Food & Marine**
Legislative authority	• 6/6 operate under a statutory basis
Inspection function (y/n)	• 6/6 have an inspection function
Selection for inspection	• 5/6 conduct inspections at defined intervals • 4/6 use risk based approach • 1/6 inspect new entities • 1/6 carry out random re-inspections • 1/6conduct random inspections • 2/6 conduct an inspection in response to a trigger or cause
Announced/ Unannounced Inspection types	• 5/6 carry out a mixture of announced and unannounced inspections • 1/6 carry out announced inspections only
Reasons given for announcing inspections	• 1/6 announces to provide notice to residents and relatives etc. • 4/6 announce to ensure key personnel are available during the inspection • 2/6 announce to ensure that required information and files are made available for the inspection • 2/6 announce to promote, ensure compliance with standards
Self-Inspection for Inspected Parties	• 1/6 self-inspection info can be used during inspection, not mandatory • 3/6 self-inspection is mandatory, reviewed during inspection as part of quality management system • 2/6 self-inspection not used
Inspection Process	• 3/6 conduct different inspection types depending on service or area being inspected (including outcomes focussed and thematic inspections) • 3/6 One inspection process for all entities

Inspection methodologies	• 5/6 assessment of systems and records associated with the activities conducted by the entity ○ 1/5 use a standardised assessment form • 1/6 inspection process based on self-assessment information provided by inspected party • 2/6 observation of practice • 2/6 meetings/ interviews with personnel

Reporting	• 6/6 issue reports to inspected party
	  ○ 1/6 reporting system involves an initial report (recommendations for corrective actions) and a final report (based on findings of follow-up inspection)
	  ○ 2/6 report outlines areas of non-compliance
	  ○ 2/6 report includes action plan outlining the action required to achieve compliance
	  ○ 1/6 report outlines the deficiencies observed during the inspection and these deficiencies are classified as critical, major and minor and the inspected party is instructed on how to respond
	• 1/6 inspection reports are peer reviewed before being issued to the inspected party
	• 5/6 reports outline a timeframe during which the inspected party must respond appropriately

Publishing of reports	• 3/6 publish reports on their websites • 3/6 do not publish reports on websites

Follow up inspections conducted (y/n)	• 6/6 conduct follow up inspections
	  ○ 1/6 always conduct follow up inspections
	  ○ 1/6 usually conduct follow up inspections
	  ○ 4/6 may conduct follow up inspections in certain instances

NOTE: The figures set out above <u>are not cumulative</u> and it is not possible to reconcile them with the total number of responses.

International Pharmacy Regulators	
Respondents (n=10)	**Pharmaceutical Services, Ministry of Health, Cyprus** **Medicines Authority, Malta** **The Finnish Medicines Agency (Fimea)** **The Pharmaceutical Society of Northern Ireland** **The State Institute for Drug Control, Czech Republic** **The State Medicines Control Agency, Lithuania** **Pharmacy Registration Board of Western Australia** **General Pharmaceutical Council of Great Britain** **Alberta College of Pharmacists, Canada** **Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI)**
Legislative authority	• 10/10 operate on a statutory basis
Inspection function (y/n)	• 10/10 have an inspection function
Selection for Inspection	• 10/10 conduct inspections at defined intervals • 6/10 conduct risk based routine compliance inspections • 3/10 conduct targeted inspections (trigger/complaint) • 2/10 Inspect new entities
Announced/Unannounced Inspection Types	• 4/10 conduct unannounced inspections only • 2/10 conduct announced inspections only with an approximate notice given - within a certain number of weeks • 4/10 conduct a mixture of announced and unannounced inspections ○ 1/4 conduct mostly unannounced but notification can be provided
Reasons given for announcing inspections	• 2/6 announce to make sure key personnel and information are available during the inspection • 1/6 announce as it is a legislative requirement to notify • 2/6 announce to give the pharmacy time to prepare for the inspection • 1/6 For pre-registration purposes

Self-Inspection for Inspected Parties	• 2/9 self-inspection tool not used
	• 7/9 self-inspection tool is used:
	  ○ 6/7 self-inspection is mandatory and is reviewed as part of the inspection process
	  ▪ 1/6 also incorporate statutory declaration of self-inspection as part of annual renewal
	  ○ 1/7 legislative requirement to conduct self-audit (not part of inspection process)

Inspection Process	• 6/9 One inspection process for all entities • 3/9 Different inspection processes used depending on area to be inspected
Inspection Methodologies	• 2/9 Inspection template is followed • 6/9 conduct an assessment of systems and records associated with the activities conducted by the entity • 1/9 use an inspection checklist • 4/9 inspection processes incorporate personnel interviewing

Reporting	• 1/9 no report issued to the inspected party
	• 8/9 issue report to the inspected party
	  ○ 7/8 structured report drawn up under specific headings (findings/areas of non-compliance/recommendations)
	  ○ 1/8 report structured so that pharmacy judged against standards & given a performance rating
	• 1/9 head of inspection reviews reports before issue to ensure consistency
	• 7/9 in the case of findings inspected parties have to respond with corrective measures within a specific timeframe

Publishing of reports	• 1/9 publish reports • 8/9 do not publish reports • 2/9 publish statistical data in relation to inspections
Follow up inspections conducted (y/n)	• 9/9 conduct follow up inspections

NOTE: The figures set out above are not cumulative and it is not possible to reconcile them with the total number of responses.
These results also include a partially completed response from the Pharmaceutical Society of Northern Ireland.

National Non-Healthcare Inspectorates	
Respondents (n=7)	**Commission Aviation Regulation (CAR)** **Central Bank of Ireland** **Department of Education and Skills** **Food Safety Authority of Ireland (FSAI)** **Garda Professional Standards Unit (GPSU)** **National Employment Rights Agency (NERA)** **Revenue**
Legislative authority	• 7/7 operate on a statutory basis
Inspection function (y/n)	• 5/7 defined inspection function • 2/7 Inspection function not defined but it is performed
Selection for inspection	• 1/7 conduct inspections at defined intervals • 6/7 use risk profiling/assessment for selection for inspection • 2/7 inspect based on random selection • 2/7 conduct targeted inspections (trigger/complaint) • 1/7 inspect new entities
Announced/Unannounced Inspection Types	• 3/7 conduct announced inspections only • 3/7 conduct a mixture of announced/unannounced inspections • 1/7 conduct announced inspections in conjunction with unannounced spot checks of records
Reasons given for announcing inspections	• 6/7 announce to make sure key personnel are available during inspection to answer questions/ queries • 4/7 announce to facilitate access to/organisation of relevant documentation • 1/7 announce to promote compliance with the legislation • 1/7 announce where re-inspection is required
Self-Inspection for Inspected Parties	• 3/7 self-inspection is not used • 2/7 self-inspection process, mandatory, used as part of inspection process • 2/7 self-inspection used under certain circumstances only

Inspection Process	• 5/7 conduct systematic inspection processes • 2/7 conduct specific inspection process types
Inspection Methodology	• 6/7 conduct an assessment of systems and records associated with the activities conducted by the entity • 2/7 conduct a "walk-through" of the premises • 4/7 conduct meetings/interviews with key personnel • 1/7 observe practice during the inspection • 2/7 provide advice on irregularities or errors during the inspection
Reporting	• 6/7 report issued to inspected party detailing the findings and recommendations • 1/7 no written report issued, but advice provided to inspected party on-site
Publishing of reports	• 6/7 do not publish reports • 1/7 publish reports on website • 2/7 publish inspection summary data
Follow up inspections conducted (y/n)	• 6/7 conduct follow up inspections • 1/7 do not conduct follow up inspections

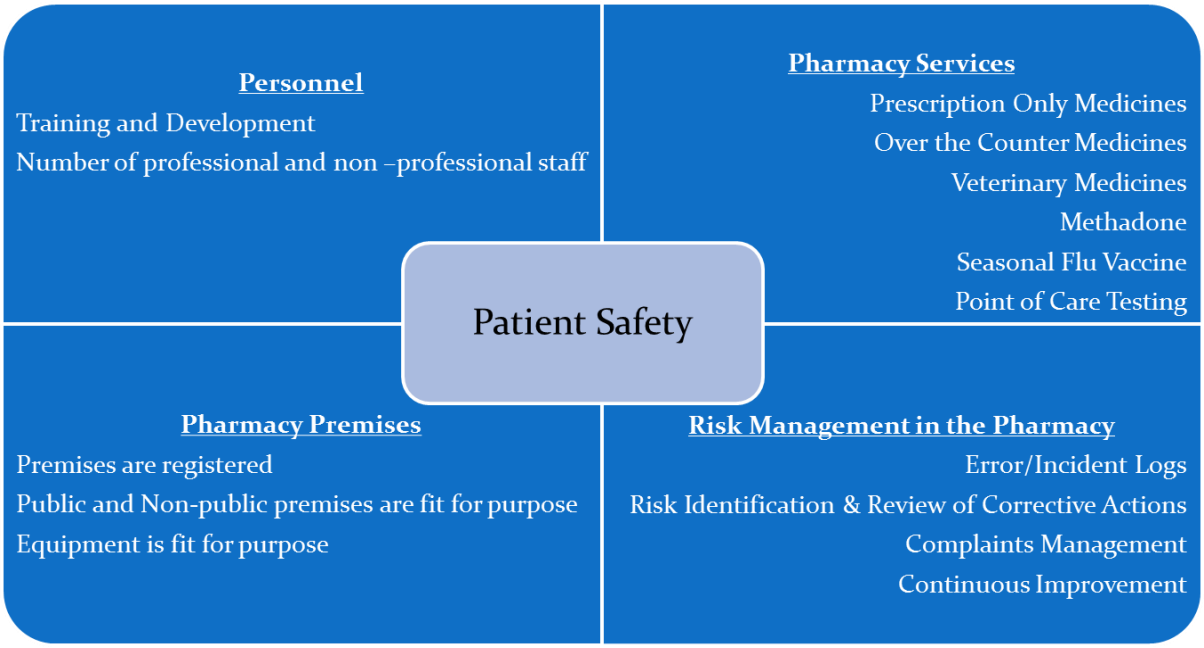
National Healthcare Regulators with no inspection function	
Respondents (n=3)	**Medical Council of Ireland** **CORU- The Health and Social Care Professionals Council** **Nursing and Midwifery Board of Ireland**
Legislative authority	• 3/3 operate under a statutory basis
Inspection function (y/n)	• 0/3 have an inspection function

Appendix 15:

Indicative Structure for a Pharmacy Self-Audit

Indicative Structure for a Pharmacy Self-Audit

The Group suggested the following indicative structure for a self-audit which would be based on the following 4 pillars each of which would be underpinned by a complete set of documented procedures and focussed on patient safety at the pharmacy.



Each pillar should include a number of key elements for review and examination in the completion of the self-audit process.

- Personnel management
  - Training and development of professional and non-professional staff at the pharmacy
  - Number of professional and non-professional at the pharmacy having regard to the level of activity at the pharmacy
- Pharmacy Services
  - Sale and supply of prescription only medicines (including to patients resident in Nursing Homes)
  - Sale and supply of non-prescription only (over the counter) medicines
  - Sale and supply of veterinary medicines
  - Supply of Methadone under the current Opioid Treatment Protocol
  - Administration of the seasonal influenza vaccine
  - Point of care testing
- Pharmacy Premises
  - Premises are registered with the PSI
  - Public and non-public premises are fit for purpose for the sale and supply of medicines
  - Appropriate equipment is available in the pharmacy and is fit for purpose
- Risk Management in the pharmacy

- Risk identification and review of corrective actions
- Maintenance of Error/Incident logs
- Complaints management
- Continuous improvement

Having regard to this basic structure comprising the 4 key pillars, the self-audit should be developed into a more substantial document to facilitate the in-depth review of the processes and procedures in place under each element.

To further illustrate its vision for a self-audit model and by way of example, the Group set out the style and content of some questions which might be posed in the self-audit template under the heading of **"sale and supply of prescription only medicines"** in the **Pharmacy Services pillar**. The Group further suggested that questions should include all legislative and PSI guidance requirements. Examples of potential questions include:

- how is the prescription handled by both professional and non-professional staff from the time the patient enters the pharmacy to the time that the patient leaves the pharmacy with their prescribed medicines?
- how is the prescription checked to ensure it is valid at the time of dispensing in accordance with the provisions set out in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended and the Misuse of Drugs Regulations 1988 as amended?
- how is the prescription reviewed by a pharmacist to check its pharmaceutical and therapeutic appropriateness in accordance with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008?
- how is the patient's electronic file updated?
- how are the relevant provisions of the Health (Pricing and Supply of Medical Goods) Act 2013 applied?
- how are the prescribed medicines assembled and labelled in accordance with the prescription?
- how is the appropriate information, advice and counselling provided to the patient ?
- how is the patient consultation area used (PSI Guidance on Patient Consultation Areas (May 2010) and Regulation 4(3) of the Regulation of Retail Pharmacy Businesses Regulations 2008?
- how are records of each medicine dispensed maintained i.e. retention of prescriptions where relevant and maintenance of the prescription register and controlled drugs registers in accordance with the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended and the Misuse of Drugs Regulations 1988 as amended?
- do the written procedures (SOPs) in place in the pharmacy accurately reflect the practices at the pharmacy?

The Group noted that this was merely a sample list (not a complete or exhaustive list) which would need considerable input from the PSI to develop a complete Self-Audit Template for Pharmacies.

Appendix 16:

Summary of the Responsibilities and Activities for the Main Players in the Pharmacy Governance and Practice Inspection

Summary of the responsibilities and activities for the main players in the Pharmacy Governance and Practice Inspection

Supervising Pharmacist

- **Complete the PSI Self Audit** every 6 months to identify non-compliances or areas for improvement and corrective actions.
- **Involve other pharmacists and staff members** in the completion of the Self-Audit.
- **Communicate and implement all observations and corrective actions** within the timelines identified.
- **Communicate** the outcome from the Self Audit with other staff members.
- Ensure that the PSI Self Audit is **stored at the pharmacy.**
- Together with the Superintendent Pharmacist and the Pharmacy Owner **review previously completed PSI Self-Audits** to verify that all identified corrective actions have been completed and to analyse trends in observations arising over time.

Superintendent Pharmacist & Pharmacy Owner

- Provide the Supervising Pharmacist with the **necessary support and resources** to complete the PSI Self Audit.
- **Review and sign off on the completed Self Audits.**
- Ensure that the necessary support and resources are provided to implement the **corrective actions identified.**

I&E Unit & PSI Inspectors

- **Schedule** routine inspections on the basis of a risk assessment
- Provide **7 days notice** to the Supervising Pharmacist.
- Conduct an inspection under **Section 67 of the Pharmacy Act.**
- **Meet** with the Supervising Pharmacist.
- **Review the Self Audits** maintained at the pharmacy **to verify that it reflects the actual practices at the pharmacy**.
- **Review other documentation** including mandatory records such as prescriptions, controlled drugs registers, prescription registers and SOPs.
- **Examine the premises and equipment in the pharmacy**
- **Observe practices and interactions with patients**
- **Request any other information or ask any other questions necessary**
- **Provide feedback** to the Supervising Pharmacist at the end of the inspection
- **Prepare a report** of the overall inspection findings .