Pharmaceutical Society NI

Protecting Registering Regulating

Fitness to Practise Report 2013

Including learnings for pharmacists

Contents

Council observations

Welcome to the Pharmaceutical Society of Northern Ireland Annual Fitness to Practise report 2013. This report contains key statistics and learning points for pharmacists arising from fitness to practise cases and issues throughout 2013.

This report has been produced in accordance with the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012.

At its meeting of 10 April 2014 the Council of the Pharmaceutical Society NI considered and approved the 2013 Annual Fitness to Practise report and in accordance with the legislation, made the following observations.

Council recognises that the period covered by the report largely relates to the introduction of new processes following legislative reform and considers that the changes allow the Pharmaceutical Society NI to protect the public more effectively and enable a more proportionate approach to the management of fitness to practise case outcomes.

This report sets out how the Scrutiny and Statutory committees, established under the new legislation, have dealt with cases brought before them and how they have utilised the full range of sanctions available to them following legislative reform.

Council will continue to explore ways to improve and develop our fitness to practise processes and in 2014 this will include, keeping under review, our case management system to ensure the most effective method is in place to assess cases and faster investigation outcomes for patients. Key Performance Indicators (KPIs) will also be reviewed to ensure that performance targets are capable of being met.

It is important that learnings from fitness to practise cases are shared to improve understanding among registrants and to enhance safe and effective practice. Council will continue monitor this to ensure that FTP learning points are captured and disseminated to relevant stakeholders in a timely fashion.

Relationships with other bodies are important in order for the Pharmaceutical Society NI to exercise our fitness to practise functions. We continue to operate the Pharmacy Network Group (PNG), a formal intelligence group which effectively coordinates the actions of all relevant bodies around pharmacy complaints.

Council will work with the Registrar to ensure that all agencies associated with complaint management work cohesively and productively to meet agreed timeframes.

1. Introduction

The Pharmaceutical Society NI is the regulator for pharmacists registered to practise in Northern Ireland. The statutory legislation pertaining to this comes from the Medicines Act 1968 and the Pharmacy (Northern Ireland) Order 1976.

On 31st December 2013 there were 2156 pharmacists and 549 pharmacy premises registered with the Pharmaceutical Society NI.

All pharmacists are regarded as practising. Currently the Pharmaceutical Society NI does not register pharmacy technicians as there is no statutory legislation to underpin this.

Details of the live register of pharmacists can be found on the web based register 'Search the Register'; by phoning the offices during working hours 9am to 5pm Monday to Friday 028 9032 6927; by writing to the registration department or emailing registration@psni.org.uk

Fitness to practise, including the receipt and processing of complaints, concerns and incidents are the responsibility of the Registrar. The current Registrar is Mr Brendan Kerr and he is legally responsible for the integrity and posting of the pharmacy registers of pharmacists and pharmacies.

2. Inspection of pharmacies and pharmacists

The Pharmaceutical Society NI does not employ its own pharmacy inspectors but works in close partnership with the Department of Health, Social Services and Public Safety (DHSSPS) Pharmaceutical Inspectorate, (the Medicines Regulatory Group) who have statutory duties under the Medicines Act 1968, the Pharmacy (Northern Ireland) Order 1976, the Poisons (Northern Ireland) Order 1976, the Misuse of Drugs Act 1971, the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The inspectors also investigate any potential breaches of the Pharmaceutical Society NI Code of Ethics[1] and published Standards and Guidance.

3. Allied healthcare bodies

The Pharmaceutical Society NI works closely with officials in the Health and Social Care Board (HSCB), the Business Services Organisation (BSO), Health and Social Care Trusts and the Regulation and Quality Improvement Authority (RQIA).

[1] Pharmaceutical Society NI Code of Ethics (2009)
http://www.psni.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf

4. Pharmacy regulation in Northern Ireland

The Pharmacy (Northern Ireland) Order 1976 was significantly amended in late January 2012 and a set of complementary new Regulations was enacted on 1st October 2012.

The Amendment Order[2] and Statutory Regulations introduce a number of processes including a greater panel for the Statutory Committee and a Scrutiny or Investigating Committee in statute. Together, the Committees have a much wider range of powers in regard to fitness to practise including; advice, warning, undertakings, suspension, interim orders and erasure or removal of registrants.

5. Fitness to Practise data for the cases considered in 2013

Year	Year opened	Closed in 2013	Percentage	Still open at 31st December 2013	Percentage
2010	2	1	3%	1	3%
2011	1	1	3%	0	0%
2012	9	5	15%	4	12%
2013	21	13	40%	8	24%
Totals	33	20	61%	13	39%

6. Source of the complaint or concern

Source	Number	Percentage
Anonymous	1	3%
DHSSPS	1	3%
Employer/agency	6	18%
Industry	1	3%
Pharmacist	1	3%
Public	14	43%
Registrar	2	6%
Self-declarations	7	21%
Total	33	100%

[2] http://www.legislation.gov.uk/nisr/2012/308/pdfs/nisr_20120308_en.pdf

7. Statistics regarding the cases

Closed cases at 31/12/2013	20 cases	
Average time to close	30	Weeks
Median time to closure	13	Weeks
Longest case	135	Weeks

Open cases at 31/12/2013	13 cases	
Average time open	51	Weeks
Median time open	38	Weeks
Longest case open	173	weeks

8. Issues examined in the cases closed

Issue	Number	Percentage
Collection and delivery	1	5%
Customer service issue	3	15%
Dispensing error moderate harm	1	5%
Dispensing without prescription	2	10%
Driving conviction	1	5%
Employing unregistered pharmacist	1	5%
High cost drugs	1	5%
No harm dispensing error	3	15%
Police caution	4	20%
Poor professional performance	1	5%
Supply issue	1	5%
Wholesaler misconduct	1	5%
Total	20	100%

9. Closure times of cases from date of opening to date of closure

Cases closed by Registrar	11 cases	
Average time to close	8	Weeks
Median time to closure	9	Weeks
Longest case	14	Weeks
Shortest case	0	Weeks
KPI closed <13 weeks	10/11	91%

Cases closed by Scrutiny Committee	4 cases	
Average time to close	20	Weeks
Median time to closure	21	Weeks
Longest case	26	Weeks
Shortest case	14	Weeks
KPI closed < 28 weeks	4/4	100%

Cases closed by Statutory Committee	5 cases[3]	
Average time to close	88	Weeks
Median time to closure	74	Weeks
Longest case	135	Weeks
Shortest case	64	Weeks
KPI closed < 42 weeks	0/5	0%

10. The Registrar

The Registrar is the complaints officer for the Pharmaceutical Society NI for the processing of complaints regarding the conduct and performance of pharmacists. He also ensures that pharmacy premises are fit for purpose.

When a complaint is made, the Registrar assesses the case against the published criteria and considers if any further referral is required. (see appendix 1).

Where the matter does not meet the published criteria, then where appropriate the case is closed by the Registrar.

The Scrutiny Committee will review a decision made by the Registrar to close a case.

[3] Legacy cases initiated before the Pharmacy Order 1976 was amended in 2012

11. The Scrutiny Committee

The Scrutiny Committee is constituted under the Pharmacy (Northern Ireland) Order 1976 amended in 2012 and the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012. The members are appointed by the Council having been recruited by an independent public appointments process in 2012 (see appendix 2).

The Scrutiny Committee has a quorum of three which must include the chair or deputy chair, a lay member and a registered member. The three members must consist of one legally qualified person [chair], one registrant and one lay person.

Meetings of the Scrutiny Committee 2013

In the period from January 2013 to December 2013, this Committee met on nine occasions and considered nine separate case files referred to it by the Registrar.

The Committee referred five cases on to the Statutory Committee and closed four cases. Three cases were closed with advice and one registrant was issued a warning.

12. The Statutory Committee

The Statutory Committee is constituted under the Pharmacy (Northern Ireland) Order 1976 amended in 2012 and the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012.

The members are appointed by the Council having been recruited by an independent public appointments process in 2012(see appendix 2).

The Committee has a quorum of three which must be one legally qualified person [chair], one registrant and one lay person.

Meetings of the Statutory Committee 2013

Interim order hearings [private]

The Statutory Committee met on five occasions to consider interim order applications by the Registrar.

One registrant received an interim suspension order made in 2012 which was reviewed and extended on two occasions in 2013, each time for six months.

One registrant received an interim conditions order which was reviewed at the full hearing and was subsequently replaced with a suspension order of one year.

One registrant received an interim suspension order for six months.

Full conduct hearings [public]

The Statutory Committee met on five occasions in 2013 holding full conduct hearings.

Registrant	Date of hearing	Outcome
Case one	04/06/2013	Advice
Case two	14/06/2013	Suspension 3 months
Case three	21/06/2013	Conditions on practise
Case four	23/07/2013	Suspension 12 months
Case five	12/08/2013	Suspension 6 months

Outcomes for all cases are listed on the Pharmaceutical Society NI website at http://www.psni.org.uk/about/fitness-to-practise/determinations-of-statutory-committee/

13. Learning points

It is our policy to share the learning from our fitness to practise investigations to improve understanding among registrants and to enhance safe and effective practice. A number of key themes emerged from cases and these are outlined below:

a) Statutory Committee cases

Case One

The Statutory Committee inquired into the supply of medication to a patient, authorised on an NHS prescription. The medications prescribed were for an infant and required the products to be dispensed extemporaneously to accommodate the required dosages for the patient.

The pharmacist made errors in calculations and the two medications were prepared incorrectly at higher dosages than those prescribed.

When dispensed to the patient's carer, the dosages were queried by the carer due to significant dose changes. The pharmacist conducted a check of the calculations previously made and verified the integrity of the dispensed product, to the patient's carer. The carer pursued further checks with secondary care providers and established the error that was made. None of the erroneous medications were administered to the infant; in this case the matter was classified as a near miss.

Outcome

The pharmacist was given advice by the Committee on observing Standard Operating Procedures (SOPs) with regard to future practice.

Learning points

1. A pharmacist has a duty of care to clinically and accurately check all medicines dispensed.

2. Where medications are compounded with respect to body weights of an infant due diligence is needed in the:
   a. assessment of the prescription;
   b. calculations undertaken;
   c. appropriateness of the medication with respect to the prescription;
   d. dosages dispensed to the patient especially when he/she is an infant.

3. Pharmacy procedures must ensure adequate quality and safety in the compounding and supply of medicines.

4. Records of all extemporaneous preparations should be made and retained for an appropriate time period to allow further audit and manage risk.
5. When a patient or carer queries a prescription supply, due diligence must be observed in any reassessment of the supply function.

6. Paediatric medications can have the potential to have greater harm for the patient when doses are incorrect.

7. A pharmacist must adhere to robust protocols and maintain clear records in order to significantly reduce risk and assure quality.

Case Two

The Statutory Committee inquired into the adulteration of NHS prescription forms by a registered pharmacist.

Prescription forms were redacted and altered to represent medications not prescribed by the originating GP.

The amended forms were faxed by the pharmacist to a UK manufacturer to verify a need for the medicines which were ordered by the pharmacy. The medications were supplied by the manufacturer in good faith in order to meet the immediate needs of patients. The pharmacist however further distributed the medications through wholesale licensed supply solely for commercial gain.

Outcome

The pharmacist's fitness to practise was found to be impaired and the Committee decided to suspend the pharmacist for a period of three months from the register.

Learning points

1. A pharmacist has no authority to amend the integrity of a prescription for any purpose or use for anything other than to supply to the patient for whom it had been written.

2. The MHRA have produced guidance on the separation of wholesaling and retailing from premises that have dual functions. Procurement of medicine stocks through the retail supply chain should be to meet immediate patient need and not for further redistribution.

3. Wholesaling should be conducted within the licence obtained from the MHRA and should also be focused on patient need. If a wholesaler chose to trade medicines for export that were in short supply in the UK and as a consequence the needs of patients in the UK are not met, the holder of a wholesale dealer licence maybe in breach of the Regulations, and could face regulatory action, and/or criminal prosecution

4. The holder of a wholesale dealer licence may only legally obtain medicinal products from licensed manufacturers or licensed wholesale dealers in the UK or other EEA Member States. A licence holder obtaining products from outside of the regulated supply chain, including obtaining stock from a pharmacy would be in breach of their licence and could face regulatory action, and/or criminal prosecution.

Case Three

The Statutory Committee inquired into the supply of medication to 42 patients by a pharmacist by way of monitored dosage systems.

The prescription only medications supplied were not all in accordance with legislation in that medicines were supplied using historical pharmacy patient histories. On occasion the medications supplied were either different to the strength or product authorised on the prescriptions. There were also instances of medications supplied in the absence of authorising prescriptions. No harm was suffered by patients. The pharmacist was prosecuted and convicted of a number of breaches of the Medicines Act 1968.

Outcome

The pharmacist's fitness to practise was found to be impaired and remained registered but subject to conditions. The pharmacist was directed to produce a personal development plan and to undertake a period of 12 months supervised practise.

Learning points

1. A pharmacist has a duty of care to clinically check all prescription medicines dispensed against the authority of the prescriptions.

2. Patient medication records are an adjunct to clinical care of patients. They do not form any authority to dispense to patients without a prescription.

3. It is high risk practise to dispense from historical pharmacy records and therefore when dispensing medication a new entry should be created in Patient Medication Records [PMRs] using the authorising prescription. Adherence to pharmacy procedures Standard Operating Procedures [SOPs] helps to quality assure the safe and effective supply of medicines.

4. Reconciliations through the audit of prescription forms and corresponding correlation with pharmacy PMR data will help affirm safe supply of medication.

Case Four

The Statutory Committee inquired into the supply of medication to several patients using monitored dosage systems [MDS]. The medications supplied were not all in accordance with statutory legislation, in that medicines were supplied only using pharmacy patient histories.

On occasions the medications supplied had been discontinued or substituted by the prescribing physician with new drug therapy. The patient subsequently received both medications.

There were also instances of medications being supplied where there were no authorising prescriptions were issued. No harm was suffered by the affected patients.

The registrant failed to engage with the regulator throughout the investigation. The outcome of the inquiry was that the pharmacist was found to be impaired and was suspended for 12 months to be reviewed at that time.

Learning points

1. A pharmacist has a duty of care to clinically check all medicines dispensed.

2. Patient medication records are an adjunct to clinical care of patients. They do not form any authority to dispense to patients without a prescription.

3. It is high risk practise to dispense off historical pharmacy records and therefore when dispensing medication a new entry should be created in PMRs using the authorising prescription.

4. Adherence to pharmacy procedures [sops] helps to assure quality the safe and effective supply of medicines.

5. Reconciliations through the audit of prescription forms and correlation with pharmacy PMR data will help affirm safe supply of medication.

6. Registrants are advised to engage with the regulator throughout fitness to practice investigations. A lack of engagement will be taken into consideration by fitness to practise panels when making a decision on impairment.

Case Five

The Statutory Committee inquired into the records relating to the supply of medications to a number of patients, from a community pharmacy, relating to medications controlled under the Misuse of Drugs Regulations.

Prescriptions were not always dispensed in accordance with the prescriber's directions. There were instances of medication subject to safe custody and/or registers being dispensed in advance of prescriptions without the authority of a prescription.

The record keeping in relation to controlled drugs prescriptions and registers was poor. No harm was suffered by patients.

Outcome

The result of the inquiry was that the pharmacist's fitness to practise was found to be impaired and was suspended for six months subject to a further review.

Learning points

1. A pharmacist has a duty of care to clinically and legally check the authority for all medicines dispensed.

2. Adherence to pharmacy procedures [SOPs] helps to assure quality in the safe and effective supply of medicines.

3. Medications which are controlled under the Misuse of Drugs Regulations are subject to greater legislative control and pharmacists should ensure that there are enhanced systems managing safety and quality in the processing of prescriptions for controlled drugs and any dispensing of same, to patients.

4. Medications requiring entries in registers should be treated with extra caution and contemporaneous records should be made. Where prescriptions are endorsed this should again be contemporaneous and reflect the prescribers instructions.

b) Cases considered by a Scrutiny Committee

A separate report from the Scrutiny Committee which is required in statute by, the Council of the Pharmaceutical Society of Northern Ireland (Statutory Committee, Scrutiny Committee, and Advisers) Regulations (Northern Ireland) 2012 at regulation 7 can be found at appendix 3.

This includes a report on:

(i) Trends, patterns and learning points observed from cases considered by the Scrutiny Committee

(ii) Details of the numbers of fitness to practise and disqualification allegations which were disposed of by the Scrutiny Committee by means of warnings and undertakings during that year, and

(iii) The reasons why the allegations referred to in sub-paragraph (ii) were not referred to the Statutory Committee.

c) Cases closed by the Registrar

i. Dispensing errors no harm

The Pharmaceutical Society NI reviewed reported dispensing errors and liaised with colleagues at the DHSSPS and the HSCB.

Where patients suffered moderate harm or greater, or there are serious departures from safe practise or recurrence of errors, the matters were passed to the DHSSPS for investigation. Service issues were referred to the HSCB. All reports produced were assessed and where it was established that the published referral criteria was met they were subsequently referred to the appropriate Fitness to Practise panel i.e. Scrutiny or Statutory Committee. Those that did not meet the referral criteria were investigated by the Registrar and closed.

There were four cases where dispensing errors had occurred that were investigated by the Registrar and closed.

An internal audit highlighted that one case which was closed by the Registrar should have been referred on to the Scrutiny Committee for its consideration as a risk assessment had identified moderate harm.

On review, the Committee agreed with the decision to close the case.

Where a pharmacist has been involved in a dispensing error he/she must always put the interests of the patient first. The practitioner should:

- Risk assess any potential health impact for the patient;
- Immediately address the issue;
- Consider an apology to the patient/carer;
- Check the health status of the patient and whether has there been any harm;
    - either by the administration of the wrong medicine; and/or
    - the absence of the medication which should have been administered;
- Direct the patient to seek immediate medical assistance, if appropriate;
- Supply the correct medication to the patient;
- Inform the patient's doctor of the incident to maintain the quality of their healthcare (this is considered good practice);
- Record contemporaneously the incident in a critical incident log;
- Conduct a full root cause analysis of what happened and why;
- Review SOPS to identify any changes if any that are required to be made and action;
- Identify any other issues requiring attention; e.g.
    - Information technology;
    - Human resources [staffing quotas];
    - Training needs;
- Report feedback about the incident to the patient;
- Report feedback about the incident to the superintendent or owner;
- Action any remedial issues identified above;
- Report to HSCB, DHSSPS or Pharmaceutical Society NI where appropriate; and
- Liaise with a medicines governance lead, where appropriate.

Where this guidance is followed, there is an opportunity for learning and *fair blame.* Patient confidence is often maintained.

There are in excess of 35 million prescription items dispensed in Northern Ireland each year. Reported dispensing errors number less than 100. The accuracy rates are extremely high but this does not leave room for any complacency and a single error can potentially cause great harm or death to a patient.

The functions of fitness to practise processes are not to punish a pharmacist but to assess risk and assure the public that the practitioner remains fit to practise. Ethically and professionally a pharmacist must evidence that their primary interest is the welfare of the patient as outlined by principle one of the Code of Ethics.

ii. Prescription collection and delivery

Collection and delivery by pharmacists has led to patients expecting medications to be constantly available for delivery by pharmacies. Where a pharmacy operates any collection and delivery services, then patients and the public should be fully informed of the operating parameters of the service and consent obtained.

The primary supply of medicines to patients authorised by prescriptions should occur in registered pharmacy premises. The patient or carer then has full opportunity to interact fully with the pharmacist in a clinical environment and with full access to patient records.

One complaint was closed by the Registrar in regard to collection and delivery

iii. Practising whilst not being registered

A pharmacist can only work in Northern Ireland if registered with the Pharmaceutical Society NI. There have been a number of recent cases where a person engaged by an employer has not been registered.

Pharmacists register annually on 1st June and if fees are not paid will be removed on 1st September each year.

Pharmacists may also have annotations on the web based register including warnings, conditions, or suspension. Where a pharmacist has been removed either voluntarily, administratively [non-payment of fees], or by FTP processes, the name of that person will NOT be found on the register.

There is an obligation on individual pharmacists and employers to ensure that they are registered if working as a pharmacist. Neglecting to do this puts patients at risk.

The online register is a live feed and is the most current form of the register available. Details posted include the name of the pharmacist, registration number, and date of registration.

See Search the Register

In 2012, a pre-registration trainee worked as a pharmacist whilst not being registered. The employing pharmacist was investigated in 2013 as to why the registration status was not verified on engagement. The case was closed by the Registrar after investigation.

It is imperative that current registration status of any person employed as a pharmacist is reviewed appropriately by employers.

iv. Customer or patient service issues

The Registrar processed a number of complaints from members of the public regarding poor professional attitude in regard to the dispensing of prescriptions or dispensing of prescription owing's or phased dispensing of prescriptions.

Pharmacists should endeavour to communicate with patients in regard to service issues in a professional manner and then check understanding to reduce the likelihood of issues escalating unnecessarily.

14. The Pharmacy Network Group (PNG)

The Pharmaceutical Society NI, DHSSPS, BSO, and HSCB in 2009 formalised a memorandum of understanding regarding the sharing of information on complaints, concerns and incidents. The organisations meet proactively to develop quality frameworks for the recording and processing of complaints, concerns, and incidents relating to pharmaceutical care.

The Pharmaceutical Society NI maintains a case management system which helps to determine the most effective method to assess an individual case and progress the efficient use of resources to enable a more efficient outcome for patients.

The Pharmaceutical Society NI, BSO, HSCB and the DHSSPS currently meet monthly to review, risk assess and action activity in relation to complaints, concerns and significant incidents.

15. Key Performance Indicators (KPIs)

In regard to KPIs and the complaints handling processes the following section details the targets and adherence to same.

Acknowledgment (5 working days)

The complaint is acknowledged by the organisation that receives the complaint. This acknowledgement will be sent to the complainant within 5 working days.
100% Met

The complaint is to be referred to the Pharmacy Network Group (PNG) within 5 working days for allocation, if this is a significant risk to the public.
100% Met

Where an issue is serious, allocation of the lead body for investigation must occur as soon as possible to ensure patient/public protection.
100% Met

Registrars Investigations (13 weeks, 65 work days)

KPI indicator 1.1

The target is to complete the investigation of the complaint/concern within 13 weeks [65 working days].

However, it is understood that some complaints are more complex and will require more detailed investigations. In addition, where information is required from other bodies or a complainant is unavailable, it may not be possible to meet the 3 month time scale.

Cases closed by Registrar	Initiation to date of closure by registrar	11 cases
Average time to close	8	Weeks
Median time to closure	9	Weeks
Longest case	14	Weeks
Shortest case	0	Weeks
KPI closed <13 weeks of final report	91%	

****Times quoted are from receipt of the complaint to closure**

Scrutiny Committee (13 weeks, 65 work days)

KPI indicator 2.6

Scrutiny Committee	From end of investigation to decision by Scrutiny Committee	9 cases
Average time to close	13.5	Weeks
Median time to closure	14	Weeks
Longest case	21	Weeks
Shortest case	6	Weeks
KPI closed <13 weeks of final report	4/9	45%

Statutory Committee 13 weeks, 65 work days)

KPI indicator 2.7

Statutory Committee	From date of referral by scrutiny to decision of Statutory Committee	5 cases
Average time to close	16	Weeks
Median time to closure	16	Weeks
Longest case	20	Weeks
Shortest case	13	Weeks
KPI closed <13 weeks of final report	1/5	20%

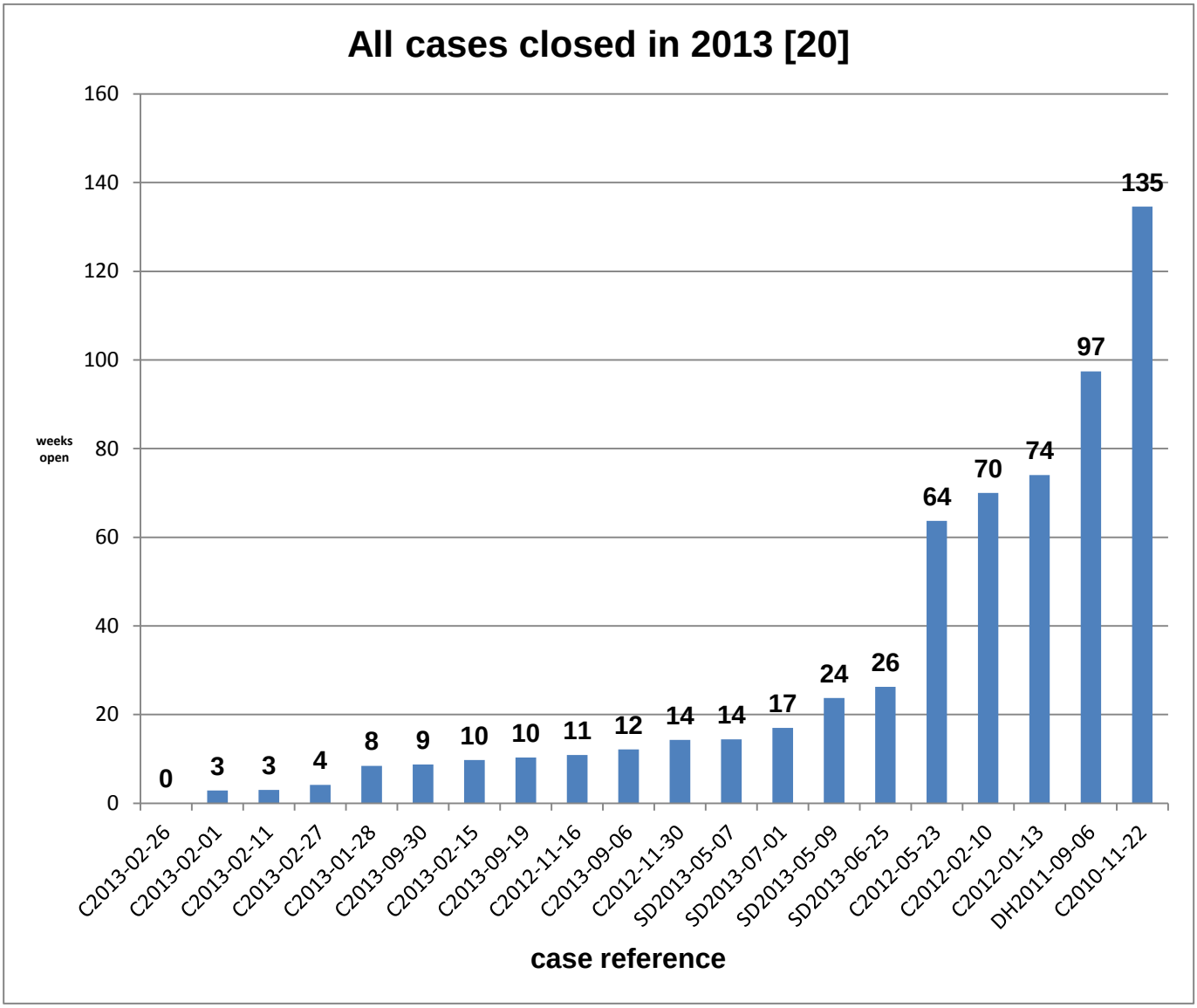
Summary of KPIs

	internal KPI's					
	factor	work days	target	total number	met kpi	percentage
	case length					
1.1	initiation to closure by registrar	<65	90%	11	10	91%
1.2	initiation to closure by scrutiny committee	<140	90%	4	4	100%
1.3	initiation to closure by statutory committee	<210	90%	5	0	0%
	administration					
2.1	complaint acknowledged	<5	100%	33	33	100%
2.2	complaint is referred into pharmacy network group where significant	<5	100%	13	13	100%
2.3	allocation of investigation external lead agreed	<3	95%	13	13	100%
2.4	report from dhssps or hscb time to closure	<60	90%	2	2	100%
2.5	report from dhssps or hscb referral to scrutiny committee	<65	90%	5	0	0%
2.6	End of investigation to consideration by a scrutiny committee	<65	90%	9	4	45%
2.7	referral from scrutiny to statutory committee	<65	90%	5	1	20%
2.8	complainant updated on mileposts	<65	90%	33	33	100%
2.9	registrant updated on mileposts		90%	33	33	100%
	case files					
3.1	closed cases reviewed	<65	100%	20	20	100%
3.2	median, and mean reviewed by council ftp committee	5	meetings	reviewed	5	100%
3.3	open cases reviewed monthly	<31	100%	13	13	100%
3.4	median, and mean reviewed by council ftp committee	5	meetings	reviewed	5	100%
	external investigations					
4.1	FTP committee updated wrt PNG activity on high risk, and or lengthy cases	5	meetings	reviewed	5	100%
	interim orders			**applied for**		
5.1	conditions orders made	1	1			
5.2	suspension orders made	4	4			
5.3	no order made	0	0			

16. Statistics relating to cases notified to the Pharmaceutical Society NI

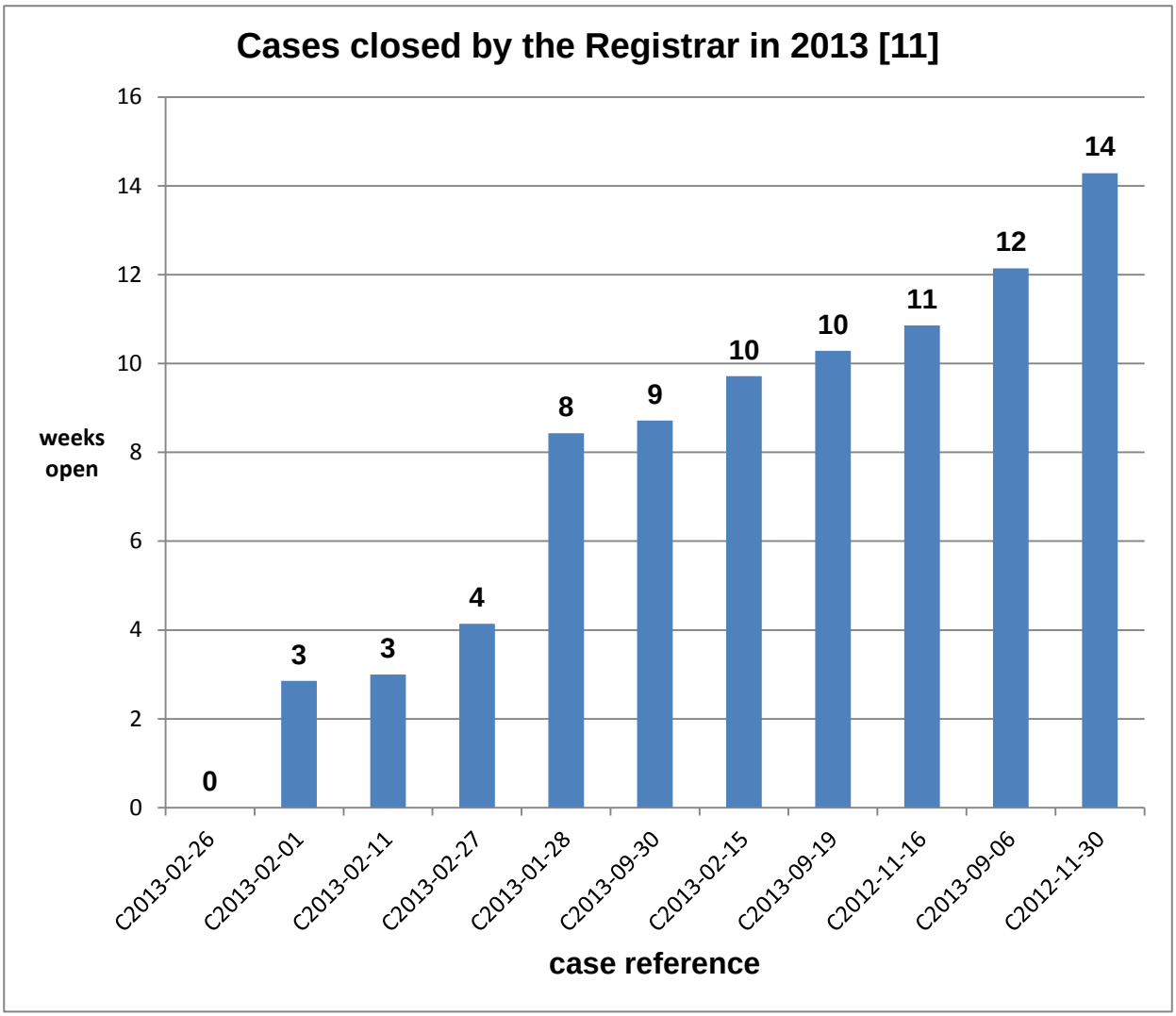
Closed cases

All case files closed in 2013 [20 cases]



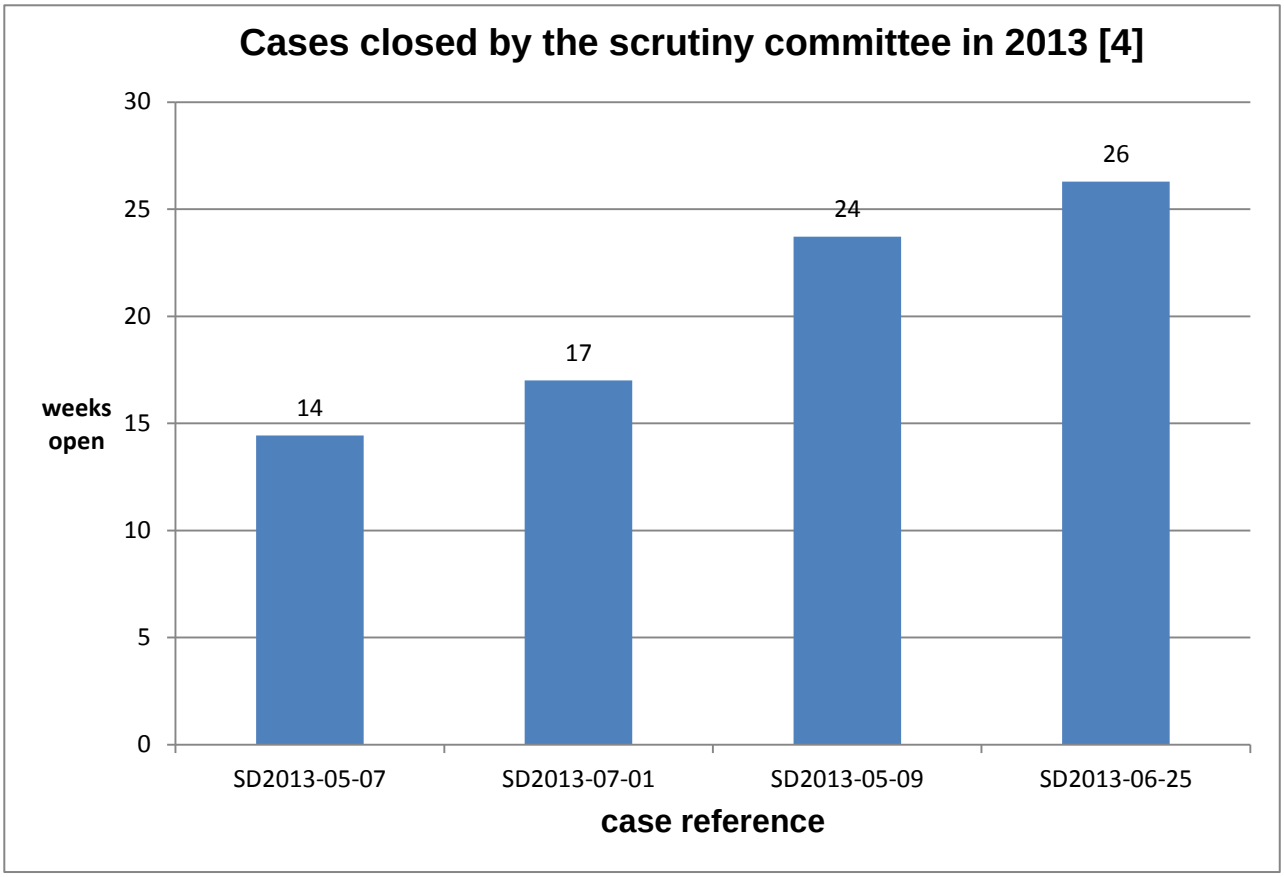
Cases closed by the Registrar in 2013 [11 cases]

KPI indicator 1.1



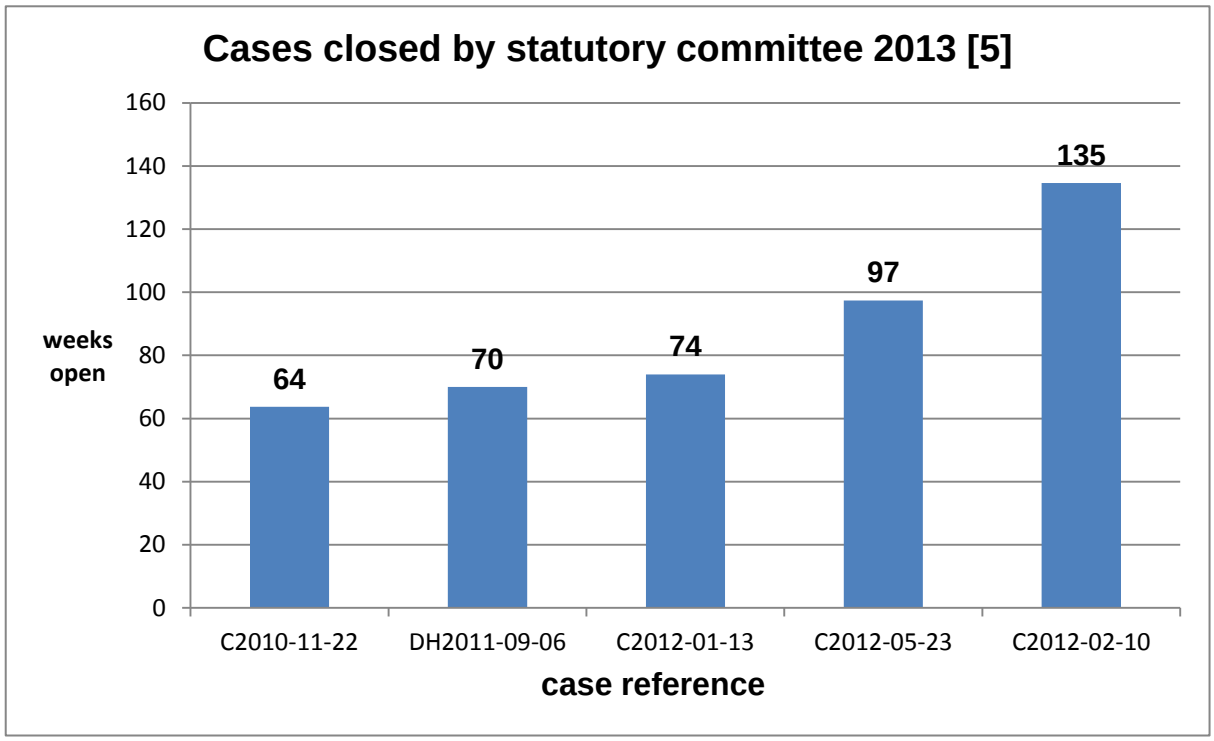
Cases closed by the Scrutiny Committee in 2013 [4 cases]

KPI indicator 1.2



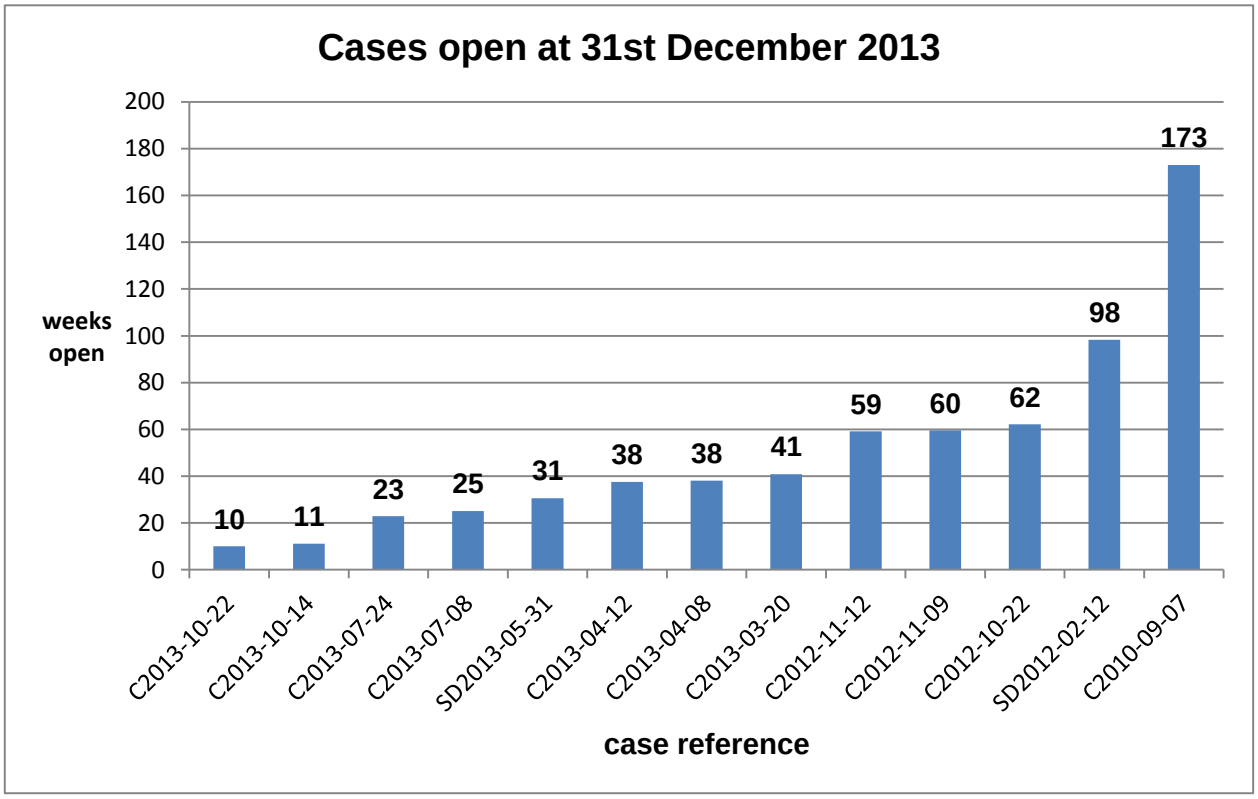
Cases closed by the Statutory Committee in 2013 [5 cases]

KPI indicator 1.3



Open cases

Case files remaining open on 31st December 2013



Appendix 1 Criteria for referral to a Scrutiny Committee

Cases are not to be referred to the Scrutiny Committee unless one of the following statements is true:

Principle 1
Make the safety and welfare of patients your prime concern

a) There is evidence that the registered person's conduct or performance caused moderate or severe harm or death, which could and should have been avoided.

b) There is evidence that the registered person deliberately attempted to cause harm to patients and the public or others.

c) There is evidence that the registered person was reckless with the safety and wellbeing of others.

Principle 2
Respect and protect confidential information

a) There is evidence that the registered person failed to respect the confidentiality of information or misused confidential information acquired in the course of professional practice to an extent likely to undermine public confidence in the profession if not challenged by the regulatory body.

Principle 3
Show respect for others

a) There is evidence that the registered person failed to respect the human rights of patients, or demonstrated in their behaviour attitudes which are incompatible with registration as a pharmacy professional.

b) There is evidence that the registered person failed to maintain appropriate professional boundaries in their relationship with patients and/or others.

Principle 4
Exercise professional judgment in the interests of patients and public

a) There is evidence that the registered person put their own interests, or those of a third party, before those of their patients.

b) There is evidence that the registered person culpably failed to act when necessary in order to protect the safety of patients.

Principle 5

Encourage patients (and/or their carers as appropriate) to participate in decisions about their care

a) There is evidence that the registered person damaged or put at significant risk the best interests of patients by failing to communicate appropriately with patients or others.

Principle 6

Maintain and develop professional knowledge and competence

a) There is evidence that the registered person practised outside of their current competence.
b) There is evidence that the registered person failed to maintain their knowledge and skills in a field relevant to their practice.
c) There is evidence of a course of conduct, which is likely to undermine public confidence in the profession generally or put patient safety at risk, if not challenged by the regulatory body.
d) There is evidence of adverse physical or mental health which impairs the registered person's ability to practice safely or effectively.

Principle 7

Act with honesty and integrity

a) There is evidence that the registered person behaved dishonestly.
b) There is evidence of behaviour on the part of the registered person which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Principle 8

Provide a high standard of practice and care at all times

a) There is evidence that the registered person has practised in a way that was systematically unsafe, or, has allowed or encouraged others to do so, where he or she has responsibilities for ensuring a safe system of working.

If the Registrar is in doubt as to whether the above criteria have been met, he shall refer the case to the Scrutiny Committee.

Appendix 2 Committee membership 2013

Scrutiny Committee
October 2013

Mr John Gibbons	Chair	Legally qualified
Ms Rosemary Connolly	Deputy Chair	Legally qualified
Mr Andrew Thomson		Lay
Mrs Jinna Brownlees		Lay
Prof Colin Adair		Pharmacist
Mr James Taggart		Pharmacist
Mrs Bronagh White		Pharmacist
Dr Dennis Morrison[4]		Pharmacist

Statutory Committee
October 2013

Mrs Gillian McGaughey	Chair	Legally qualified
Mr Michael Wilson	Deputy Chair	Legally qualified
Mr Kevin Neary	Deputy Chair	Legally qualified
Ms Miriam Karp		Lay
Mrs Carol Ackah		Lay
Mr Eoin Doyle		Lay
Mr Michael Hamill		Pharmacist
Dr Sheelagh Hillan		Pharmacist
Ms Jane Laughlin		Pharmacist
Mr John McClintock		Pharmacist
Mrs Cathy Wilkinson		Pharmacist
Mrs Mary Jane Biggart		Pharmacist

[4] Retired June 2013

Appendix 3 **Scrutiny Committee Annual report 2013**

Scrutiny Committee

Annual Report 2013

Introduction

One of the requirements of the new legislation introduced in 2012 is the provision by the Scrutiny Committee to the Council of the Pharmaceutical Society NI, of an annual report.

This is provided for by the 'The Council of the Pharmaceutical Society of Northern Ireland (Statutory Committee, Scrutiny Committee and Advisers) Regulations (Northern Ireland) 2012', wherein it states as follows;

7.—(1) The Scrutiny Committee has the following additional functions—
(a) providing an annual report to the Council in respect of each calendar year, by a date specified by the Council, which is to include
(i) trends, patterns and learning points observed from cases considered by the Scrutiny Committee,
(ii) details of the numbers of fitness to practise and disqualification allegations which were disposed of by the Scrutiny Committee by means of warnings and undertakings during that year, and
(iii) the reasons why the allegations referred to in sub-paragraph (ii) were not referred to the Statutory Committee;

This is the first such report and covers the calendar year of 2013. The new committee came into existence in late 2012, during which period training for all members was undertaken.

Composition of the Scrutiny Committee

The statutory Scrutiny Committee was appointed on 1 October 2012 and consists of a publicly recruited panel, trained in fitness to practise proceedings.

Chair and legally qualified member	Mr. John Gibbons
Deputy chair and legally qualified member	Ms. Rosemary Connolly
Lay member	Mr. Andrew Thomson
Lay member	Ms. Jinna Brownlees
Pharmacist member	Mrs. Bronagh White
Pharmacist member	Prof. Colin Adair
Pharmacist member	Mr. James Taggart
Pharmacist member *(Resigned in June 2013)*	*Dr Denis Morrison*

Background

By way of background, following the enactment of new legislation in October 2012, additional powers enable the Pharmaceutical Society NI to take more proportionate approaches to the management of fitness to practise case outcomes than simply removal from the register.

The new powers in regard to fitness to practise mean that as a regulator the Pharmaceutical Society NI can:

- Give advice,
- Issue formal warnings,
- Agree undertakings,
- Place conditions on the practise of a pharmacist,
- Impose suspension,
- Issue interim orders and
- Remove registrants from the register.

Fitness to Practise Committees

Under the new legislation, two committees have been established which determine allegations regarding fitness to practise.

Scrutiny Committee (Initial Proceedings)

This committee considers initial allegations on a paper based format and it has the power to dismiss a case, give advice, issue warnings and agree undertakings if appropriate and refer more serious cases to the Statutory Committee (subject to threshold criteria).

Statutory Committee (Hearings Committee)

This committee considers allegations at hearings of misconduct of registered pharmacists. Registrants are invited to make representations with legal support if necessary.

The Statutory Committee deals with all categories of alleged impairment referred to it by either the Registrar or the Scrutiny Committee and may utilise the full range of fitness to practise sanctions i.e. Give advice, issue formal warnings, agree undertakings, place conditions on the practise of a pharmacist, impose suspension and remove registrants from the register. It also deals with interim orders, restoration applications and review hearings.

The work of the Scrutiny Committee 2013

The committee first sat in March 2013, by which time a small backlog of cases had accumulated for consideration.

Five cases were dealt with in March, and a total of nine cases were dealt with in the full calendar year. A short summary of these cases can be found at Appendix four, detailing the registrant, the date of hearing, composition of the committee panel, the category of complaint and the method of disposal.

To better understand the reasoning of the Scrutiny Committee, in such cases, the 'Threshold Criteria' for referral to the Statutory Committee are set out in full at Appendix five hereto.

These criteria guide the Scrutiny Committee as to how to assess which cases are more serious and deserving of consideration by the Statutory Committee.

In each of the nine cases, a full reasoned written decision is provided by the Legal Chairperson setting out how these criteria have been applied in each case, after deliberation by the committee.

In five of the nine cases, the Scrutiny Committee concluded that the threshold for referral on to the Statutory Committee had been met. In the remaining four cases it was felt that the Scrutiny Committee was able to deal with those matters, using the powers granted to it by the legislation.

Further information on those matters is necessarily provided later, in the section of this report under Regulation 7(1) a (iii).

Statutory purpose of this report

1. Regulation 7(1) a (i): 'Trends, Patterns and Learning Points'

As required by the legislation mentioned earlier, the first objective of this report is to identify 'trends, patterns and learning points' and bring these to the attention of the Council of the Pharmaceutical Society NI, with a view to enabling issues to be identified at as early a stage as possible.

Trends and Patterns

The Scrutiny Committee was of the view that the cases referred to it had such divergent factual circumstances that it was difficult at this early point in its work to say that any particular trends and or patterns of behaviour were obvious, that would require comment, or to be brought to the attention of the Council of the Society.

There were a number of cases that involved relatively minor offending, as regards alcohol and/or road traffic offences. However, this will inevitably occur when considering a body of people of the size of the profession, and the Committee could not say that they found any unusually high level of offending behaviour, of any particular category.

Learning Points

Each panel considering a case will comprise a Legal Chair, a Lay member and a Pharmacist member. The pharmacist members of each panel were asked to comment on any learning points they felt had arisen in each case they were involved in, as they were felt to be best placed to comment on what may or may not be the considered view of the average member of the profession.

Other members were asked to put forward any points they felt may be relevant, from their more general experience. Below is a summary of the points made by committee members, as to what could be considered learning points.

These are issues which may already be addressed in training and guidance given to the profession, but as they have arisen in the context of the caseload of the committee, these may be areas where further emphasis may be needed. That would be a matter for the Society to consider.

Learning Point One

Pharmacists who have wholesale dealer licenses have a duty to ensure the appropriate and continued supply of medicinal products within the supply chain so that the needs of patients in the UK are met.

If a pharmacist with a wholesaler licence chooses to trade in medicines for export that are in short supply and as consequence the needs of UK patients are not met then the pharmacist could be in breach of the Human Medicine Regulations.

Dealing in medicines through the wholesale route for short term financial gain may be judged to be contrary to acceptable professional behaviour and/or is activity that may be considered to bring the profession into disrepute

Pharmacists should ensure that their professional judgment is not affected by personal incentives through the re-distribution of medicines.

Pharmacists have no authority to amend a prescription other than to ensure the safe supply of medicine to the patient for whom the prescription had been written.

Learning Point Two

In one case the pharmacist supplied Prescription Only Medicines to patients without receipt of prescription contrary to Section 67(2) of the Medicines Act, in doing so he failed to check the clinical appropriateness of the prescribed medication and the fact that the patient could be harmed by taking the medicines prescribed.

As a healthcare professional a pharmacist should seek appropriate verification from the prescriber, when there is any room for doubt and make contemporaneous records of any dialogue.

It is important to record any decision to supply or not to supply against the prescription. Patient Medication Records do not give pharmacists the authority to dispense medicines without a prescription. Dispensing medication using PMRs puts the safety and welfare of the patient at risk.

Adherence to pharmacy standard operating procedures for the safe and effective supply of medicines will ensure the quality of service provision and the reduction of risk to the patient.

Learning Point Three

Pharmacists have a professional obligation to declare any conviction, caution, or matter pending to the Registrar within seven days of the event.

A number of cases were referred to the Scrutiny Committee by the registrar due to a pre-registration students getting into trouble with the Police for minor criminal offences such as disorderly behaviour and obstructing police.

Another case involved an experienced pharmacist in a reasonably serious road traffic offence. The profession should be aware that any acts that call into question the professionalism or the performance of the registrant will be investigated to ensure that the registrants fitness to practice is not impaired and pharmacists are reminded that a high standard of professionalism is required both within and without pharmacy practice so as not to bring the profession into disrepute

Such offences may relate to their professional practice or personal life. Investigation is not confined to the Police Service of Northern Ireland, but could also include investigations by other public bodies such as the DHSSPS and RQIA.

While fixed penalty road traffic offences need not be declared, more serious road traffic offences, such as careless/dangerous driving and driving when unfit through drink/drugs, leading to a court conviction, must be declared.

Undergraduate pharmacy students are reminded that their actions as a student can impact on their future registration as a pharmacist with the Pharmaceutical Society NI. For example, conviction for an offence while an undergraduate must be declared at the time of registering as a pre-registration trainee. If of sufficient gravity, a conviction could prevent or delay their registration as a pharmacist. This includes seemingly trivial 'student' situations, such as a conviction for consuming alcohol in public.

Pharmacists who are the subject of a Scrutiny Committee hearing are advised that fully co-operating with the Pharmaceutical Society NI is the most effective way for the person concerned to demonstrate remorse and that they have accepted the seriousness of the incident and display insight with regard to the way in which the Pharmaceutical Society must deal with such matters.

2. Regulation 7(1)a(ii): 'Details of disposals by warnings and undertakings'

As required by the legislation mentioned earlier, the second objective of this report is to identify those cases where the Scrutiny Committee felt able to dispose of the case by way of warnings and/or undertakings, rather than refer the case onto the Statutory Committee for disposal.

Inevitably, there will be cases that fall into this category. The new legislation has established 'referral criteria', and *only* those cases that meet the referral criteria, should be referred on to the Statutory Committee. By definition, these will be the more serious cases.

The Scrutiny Committee will therefore receive less serious cases that do not pass the threshold for referral to the Statutory Committee, yet demand suitable censure or response on behalf of the Council of the Pharmaceutical Society NI.

The purpose of this part of the annual report is to inform the Council of the Pharmaceutical Society NI of the detail of such cases.
There were four such cases, three of which resulted in advice about future conduct being given, whilst the fourth case resulted in a formal warning. These cases are identified in the report.

3. Regulation 7(1)a(iii): 'Reasons for non referral to Statutory Committee'

The Scrutiny Committee is obliged to explain, in this third part of the report, the reasons why the four cases mentioned above did not pass the threshold for referral to the Statutory Committee. The purpose of this is to satisfy the Council of the Pharmaceutical Society NI that the Scrutiny Committee is exercising its powers in an appropriate way.

For example, if the Council of the Pharmaceutical Society NI was concerned that the Committee was being too lenient in the way it disposed of any particular case or category of case, then the reasoning of the Committee should be readily available to be understood and explored.

This year, the four cases disposed of by way of advice or warning all fell into the category of case where the registrant had been involved in criminal proceedings of a relatively minor nature. In each case the Committee considered that the cases were serious enough by reference to the

threshold criteria that the Registrar was correct in referring them to the Scrutiny Committee in the first place.

The Scrutiny Committee must not refer a fitness to practice allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registrant's fitness to practise is impaired. Each of the cases below had its own unique factual matrix, with mitigating factors in play.

A summary of the reasoning of the Committee in each case is set out below:

Registrant A

In this matter the registrant was a student who had been convicted and fined in relation to an offence of consuming alcohol in a public place. The relevant criteria for referral, was that he had brought the profession in to disrepute.

The Committee felt that the registrant had brought the profession into disrepute by his disregard for his legal and ethical obligations. However, the Committee felt that, although it was concerned with regard to the behaviour and conduct of the person concerned, this behaviour fell short of requiring a referral to the Statutory Committee.

The Scrutiny Committee took into account the following mitigating factors:-

- The Committee noted that there was no evidence of any further instance of similar behaviour in the period of time between the conviction in 2010 and its consideration of the matter in September 2013;

- The Committee carefully considered a letter submitted by the person concerned, and noted their expressions of regret and their frank acknowledgment of the conviction;

- The Committee noted the indication of the person concerned, had demonstrated insight by acknowledging that their actions had been inappropriate, immature and fell below what he understood would be the requirements of the Society, and indeed of himself;

- The Committee also had the benefit of a character reference provided by a Professor from the School of Pharmacy Queen's University in Belfast, which confirmed that the person concerned regretted the events of November 2009 and their belief that they now fully understood the conduct that is required of a pharmacist;

- The Committee also took careful note of the character reference provided by the pre-registration tutor of the person concerned, and of the observations made by them based on their assessment of the person concerned over a period of three years.

Registrant B

In this matter the registrant was a student, who had received a police caution in relation to an offence of possession of a small amount of cannabis. The relevant criteria for referral, was that the person concerned had brought the profession in to disrepute.

The Committee felt that the registrant had brought the profession into disrepute by their disregard for their legal and ethical obligations. However, the Committee felt that, although it was concerned with regard to the behaviour and conduct of the person concerned, this behaviour fell short of requiring a referral to the Statutory Committee.

The Scrutiny Committee took into account the following mitigating factors:

- The age of the person concerned;
- The stage of their career;
- The explanation and admissions given, (including the personal difficulties surrounding their father's illness),which were accepted;
- The remorse and the insight thereby demonstrated;
- The likelihood of any repeat behaviour (considered to be very low).

Registrant C

In this matter the registrant was a student, who had been 'Bound over to keep the peace' in relation to an offence of disorderly behavior and obstructing police.

The relevant criteria for referral, was that the person concerned had brought the profession in to disrepute. The Committee felt that the registrant had brought the profession into disrepute by their disregard for theirs legal and ethical obligations. However, the Committee felt that, although it was concerned with regard to the behaviour and conduct of the person concerned, this behaviour fell short of requiring a referral to the Statutory Committee.

The Scrutiny Committee took into account the following mitigating factors:

- The age of the person concerned;
- The stage of their career;
- The statement of the person concerned, that their actions had been 'completely
    - out of character' and assurances that they would 'never be repeated again', which
    - was accepted;
- The remorse and the insight thereby demonstrated;
- The likelihood of any repeat behaviour (considered to be very low).

Registrant D

In this matter the registrant had not practised as a pharmacist for a number of years. The person concerned had been convicted and fined in relation to offences of driving whilst unfit and dangerous driving. The relevant criteria for referral, was that they had brought the profession in to disrepute.

The Committee felt that the registrant had brought the profession into disrepute by their disregard for their legal and ethical obligations. However, the Committee felt that, although it was concerned with regard to the behaviour and conduct of the person concerned, this was a rather unusual case and fell short of requiring a referral to the Statutory Committee.

The Scrutiny Committee took into account the following mitigating factors:

- The indication that the registrant was not an active registrant and wished to
    - withdraw from the register;

- The person's lengthy unblemished driving record;

- Medical evidence 'which indicated a recovering picture of excessive alcohol intake
    - rather than a deteriorating pattern' and therefore the panel were satisfied that it is
    - unlikely that the person concerned suffered from a chronic alcohol problem;

- The remorse and the insight demonstrated;

- The likelihood of any repeat behaviour (considered to be very low);

- That the registrant's request to be removed from the register was appropriate and
    - would be completed as soon as possible;

- That in other circumstances, (if this were a case involving a practising registrant who
    - wished to remain on the register), they may have had to deal with this case more stringently.

Conclusion

I hope that this report will provide a useful insight into the work of the Scrutiny Committee in the past year, and reassurance to the Pharmaceutical Society NI that these important issues are being addressed in accordance with the new legislation, and in a satisfactory and proportionate way.

As Chair, I am pleased that my colleagues and I have dealt with the cases in a timely and professional way and to a high standard.

Accordingly, I commend the report to you.

Finally, a word of thanks…As Chair of the Scrutiny Committee I can report that the Committee members have found the work they have been tasked with, to be challenging, varied and interesting.

We have benefitted greatly from the training and assistance provided by the Pharmaceutical Society NI, together with the dedicated and professional preparatory work carried out by the administration office, to who we owe a debt of gratitude.

John Gibbons
Chair of the Scrutiny Committee

20th March 2014

Appendix 4 Meetings of the Scrutiny Committee 2013

Date of Meeting	Chair	Lay member	Pharmacist member	Description	Disposal
04/03/2013	John Gibbons	Jinna Brownlees	Colin Adair	13 convictions supply w/o scripts	Referral to Statutory Committee
05/03/2013	Rosemary Connolly	Andrew Thomson	Denis Morrison	Dispensing error involving vulnerable patient	Referral to Statutory Committee
06/03/2013	John Gibbons	Andrew Thomson	Bronagh White	Falsifying prescriptions to obtain wholesale items	Referral to Statutory Committee
25/03/2013	John Gibbons	Jinna Brownlees	Bronagh White	Supply without script, dispensing error	Referral to Statutory Committee & recommended interim order
27/03/2013	Rosemary Connolly	Andrew Thomson	Denis Morrison	Poor record keeping, no engagement with Society	Undertakings proposed - no response, referred to Statutory Committee
29/07/2013	John Gibbons	Andrew Thomson	James Taggart	Police Caution - possession of class B drug	Warning
11/09/2013	Rosemary Connolly	Andrew Thomson	Colin Adair	Conviction - consuming intoxicating liquor in public	Advice
28/10/2013	Rosemary Connolly	Jinna Brownlees	Bronagh White	Bound Over - Drunk and Disorderly	Advice
12/12/2013	John Gibbons	Jinna Brownlees	Colin Adair	Convictions - Drink driving & dangerous driving	Advice

Appendix 5 Referral criteria to a Statutory Committee

3.1 In considering individual cases the Scrutiny Committee should have regard to the principles and obligations set out in the Code of Ethics (which sets out the standards relating to the conduct, ethics and performance expected of registered persons).

3.2 Regard should also be had to the fitness to practise criteria contained within Regulation 4 of the FtP Regulations 2012. This states that the Statutory Committee:

"...must have regard to the criteria specified in paragraph (2) or, where appropriate, (3), or, where appropriate, paragraphs (2) and (3), when deciding, in the case of any registered person, whether or not the requirements as to fitness to practise are met in relation to that registered person.

(2) In relation to evidence about the conduct or behaviour of the registered person which might cast doubt on whether the requirements as to fitness to practise are met in relation to the registered person, the Statutory Committee must have regard to whether or not that conduct or behaviour –

a. presents an actual or potential risk to patients or to the public;
b. has brought, or might bring, the profession of pharmacy into disrepute;
c. has breached one of the fundamental principles of the profession of pharmacy as defined in the standards; or
d. shows that the integrity of the registered person can no longer be relied upon.

(3) In relation to evidence about the registered person's physical or mental health which might cast doubt on whether the requirements as to fitness to practise are met in relation to the registered person, the Statutory Committee must have regard to whether or not that evidence shows actual or potential –
a. self-harm; or
b. harm to patients or to the public."

3.3 In addition to 3.1 and 3.2 above, regard should also be had to the following criteria listed below. It is important to bear in mind that this does not purport to be an exhaustive list and the Scrutiny Committee may properly take into account all relevant factors relating to the particular circumstances of an individual case.

The Scrutiny Committee in performing its task should have regard to the following:

CONDUCT

Conduct which involves discrimination on grounds prohibited by law
The extent of (or if relevant, the lack) of cooperation by the registered person with any inquiries into their conduct
How long ago the relevant conduct took place
Whether the relevant conduct involves an abuse of trust or position
Whether the registered person has not complied with advice given by the Registrar of the Pharmaceutical Society of Northern Ireland or a Pharmacy Inspector
The extent to which the conduct is characteristic of the registered person or is indicative of a propensity to commit such conduct
Any efforts (or if relevant, the lack) of rehabilitation by the registered person since the conduct took place
The registered person's insight (or lack of insight, where relevant) in relation to their misconduct
Any warnings, agreed undertakings, sanctions or advice relating to the same or similar conduct given by a pharmacy regulatory body or the Health and Social Care Board in the 5 years preceding the conduct
Whether there has been an attempt to impede/obstruct a relevant investigation into the alleged conduct
Whether the registered person put their own interests, or those of a third party, before those of their patients
Whether there has been a failure to maintain appropriate professional boundaries in a relationship with patients and/or others
Conduct which may indicate an intention to disregard provisions of the 1976 Order and legislation made under it.
Whether there may have been a deliberate or serious breach of the Code of Ethics and / or other supplementary guidance published by the Pharmaceutical Society of Northern Ireland.
Whether the registered person damaged or put at significant risk the best interests of patients by failing to communicate appropriately with patients or others

PHYSICAL OR MENTAL HEALTH

Whether the condition is episodic or recurrent
Whether the condition has been sustained over a protracted period of time
Whether the registered person has sought help or has complied (or has not, where relevant) with treatment or support for their condition
The registered person's insight (or lack of insight, where relevant) in relation to their condition
Any previous findings of misconduct in relation to the registered person's physical or mental health
Whether there has been a breach or failure to comply with any previous written undertakings
Whether there has been an attempt to deliberately conceal the condition

3.4 The Scrutiny Committee should also take into account public interest considerations. This may include (but is not limited to) the maintenance of public confidence in the profession; declaring and upholding proper standards of conduct; and the protection of members of the public.

These in turn will need to be balanced against the registered person's own interests.