Pharmaceutical Society NI

Protecting Registering Regulating

Fitness to Practise Report 2014

Including learning points for pharmacists

Date of Publication 13th May 2015

Contents

Council Foreword

The Pharmaceutical Society of Northern Ireland Annual Fitness to Practise report 2014 contains key statistics and learning points for pharmacists arising from fitness to practise cases and issues throughout 2014.

This report has been produced in accordance with the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012. At its meeting on 12 May 2015 the Council of the Pharmaceutical Society NI considered and approved the 2014 Fitness to Practice Report and, in accordance with the legislation, made the following observations.

The Council remain aware of the fact that this present Report continues to reflect changes to the Fitness to Practice processes arising from legislation introduced in 2012. These changes provided the Pharmaceutical Society NI with a broader and more appropriate range of sanctions and actions open to it but which also provided the scope for demonstrating enhanced means of protecting the public. As part of this ongoing development, Council at its meeting of 03 February 2015 revised Key Performance Indicators (KPIs) to introduce a set more in keeping with the sphere of control available to the organisation and more in line with those of other Healthcare Regulators. These new KPIs will be routinely reviewed in order to streamline processes. This present Report, however, is based solely upon the previous set of Indicators.

The Council also affirms its commitment to continuing to improve and develop fitness to practice processes, building on the improvements identified and introduced to Case Management processes, following previous Audits and learnings from experience. It also believes that the speedy and accurate investigation of complaints will enhance outcomes for the public and registrants and remains committed to the streamlining of those processes, consistent with proper and equitable examination. In so doing, it recognises the challenges of resourcing both the investigation and hearing processes and the importance of capturing and disseminating the valuable lessons learnt from Fitness to Practice cases. The Council will seek to ensure that all such learning points are made available to Registrants in a timely manner.

Relationships with other bodies remain a vital aspect of the delivery of the Fitness to Practice regime. Representation within the Pharmacy Network Group allows the Pharmaceutical Society NI to remain in a position to share usefully, to collect relevant intelligence and to influence others. Consideration is also being given to re-establishment of a network of leads of Fitness to Practice within Healthcare Regulators and Council endorsees PSNI involvement in this.

During 2014 the Pharmaceutical Society NI has, at the Council's behest, significantly enhanced its governance and auditing arrangements. Council, as regards Fitness to Practice, recognises the importance of proportionate external examination of cases and seeks continuing improvements from this area. The PSA in its audit published in October 2014 concluded that that the PSNI's closure decisions posed no significant risk to public protection or public confidence in the profession and the system of regulation. The introduction of an enhanced Internal Audit function is also welcomed, in recognition of the process improvements it has and will continue to identify.

The Council notes the significant increase in the number of cases commenced in 2014 and considers this to be a by-product of the new powers available since late 2012. It believes this may be a recurring issue and places more importance on continuing improvement of processes, investigations and Hearings in delivering a robust and efficient consideration of these matters. The Council will work with the Senior Management Team and especially the Registrar in ensuring delivery in this area.

The Report, as in previous years, also sets out how the Scrutiny and Statutory Committees have conducted their business, independently of the Council and utilising fully the wider range of sanctions and findings available to them and thus enhanced outcomes for the public.

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 2014 there were 2231 pharmacists and 551 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. Pharmacy students [trainees] are registered in NI but are not subject to fitness to practise procedures.

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. Where this is a complaint or concern which needs to be addressed then the person(s) should phone the registrar at 02890326927 or write to 73 University Street Belfast, the complaints department or email to complaints@psni.org.uk any contact will be acknowledged within 3 working days.

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 and enforcement agencies

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

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, the Department of Health Social Services and Public Safety and the Regulation and Quality Improvement Authority (RQIA).

We also work closely with the Police Service of NI and with the Medicines Healthcare products Regulatory Agency (MHRA).

4. Pharmacy regulation in Northern Ireland

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

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 2014

Year 2014	Cases opened in this year	Percentage of total cases	Cases closed in 2014	Cases closed as a % of total cases	Cases still open at 31st December 2014	Cases still open as a % of total cases
2010	2	5%	1	3%	1	3%
2011	1	3%	1	3%	0	0%
2012	4	11%	4	11%	0	0%
2013	6	16%	4	11%	2	5%
2014	24	65%	12	32%	12	32%
Totals	37	100%	22	60%	15	40%

The table illustrates the 37 case files which were considered in 2014.
The 2014 data is similar to the statistics reported for the year 2013 when there were 33 cases examined.
The 2014 data also details the year in which each case was opened.
There are a number of the cases which commenced from 2010 onwards in which the registrants were subject to a FTP regulatory investigation, and also investigation by the Police Service of Northern Ireland and/or prosecution by the Public Prosecution Service, relating to criminal activity.
In these instances the criminal investigations took precedence and had to be completed before the matters could then be processed by the healthcare regulator, with regard to potential current impairment of fitness to practise.

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

6. Source of the complaint or concern

Source	number	Percent
DHSSPS	2	5%
Employer	6	16%
Regulator	1	3%
HSCB	5	13.5%
Public	15	40.5%
Other Pharmacy	1	3%
Self-Declared	7	19%
Totals	37	100%

7. Statistics regarding the cases

Closed cases at 31/12/2014	**22 cases**	
Average time to close	58	Weeks
Median time to closure	33	Weeks
Longest case	192	Weeks

Open cases at 31/12/2014	**15 cases**	
Average time open	43	Weeks
Median time open	35	Weeks
Longest case open	214	weeks

8. Issues examined in the cases closed

Issue	Number	Percentage
Conviction driving [alcohol related]	1	4.5%
Conviction [pornography related]	1	4.5%
Conviction [theft related]	2	9%
Dispensing error moderate harm	2	9%
Dispensing error no harm	12	55%
Drug misuse	1	4.5%
Clinical performance issues	2	9%
Police investigation [no action]	1	4.5%
Total	22	100%

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

Cases closed by Registrar	**7 cases**	
Average time to close	34	Weeks
Median time to closure	18	Weeks

Longest case	131	Weeks
Shortest case	11	Weeks
KPI closed <13 weeks	2/7	29%

Exception report
The cases examined by the registrar included one case which was subject to an extended police investigation and led to a closure time of 131 weeks. If this outlier was removed, the figures for the six other cases would display as average 18, median 17 & longest 28.

Cases closed by Scrutiny Committee	**9 cases**[3]	
Average time to close	35	Weeks
Median time to closure	29	Weeks
Longest case	89	Weeks
Shortest case	17	Weeks
KPI closed < 28 weeks	4/9	44%

Exception report
The cases examined by the Scrutiny Committee included one case which was extended to also investigate the activities of three other regulated pharmacists this contributed to a closure time of 89 weeks. If this outlier was removed, the figures for the eight other cases would display as average 28, median 28 & longest 43.

Cases closed by Statutory Committee	**6 cases**	
Average time to close	120	Weeks
Median time to closure	109	Weeks
Longest case	192	Weeks
Shortest case	78	Weeks
KPI closed < 42 weeks	0/6	0%

Exception report
The cases examined by the Statutory Committee included two health/conduct cases and four cases which were subject to extended police investigations. In two of these cases the registrants were suspended from the register for 12 months prior to being removed.
If these two case outliers had the times reported adjusted to remove the 12 month suspensions, then the figures for the six cases would display as average 103, median 100 & longest 140.

The Council reviewed in September 2014 the suitability of the KPIs reported on in this report and in this review considered these should be amended to better reflect appropriate times for case closures which were in keeping with the other healthcare regulators. A mapping was conducted late in 2014 and the Council will next publish

[3] One anonymous case was additionally considered by the scrutiny committee in their review of a case regarding a registrant

new KPIs for the investigative process in early 2015 with a commitment to monitor and review these. Specifically the Council wish to address the KPIs set for those parts of the investigative process over which we have no operational control e.g. police investigations, and describe how these are reported on within new KPIs.
In the second half of 2014 the organisation has implemented new case management processes to manage risk and affect better timeliness. We have also invested in additional staffing to facilitate these investigation processes.
Learnings from oversight of FTP processes are reported on within this report and in newsletters issued through the year.

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)[4].
Where the matter does not meet the published criteria, then where appropriate the case is closed by the Registrar.
The CEO reviews decisions made by the Registrar to close a case.

4 Referral criteria by the registrar to a scrutiny committee were updated in August 2014

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.

Each Scrutiny Committee chair reviews the closures of the other chair for learnings and process mapping.

Meetings of the Scrutiny Committee 2014

In the period from January 2014 to December 2014, the Committee met on 5 occasions and considered 9 separate case files referred to it by the Registrar.

The Committee referred no cases on to the Statutory Committee and closed 9 cases. 4 cases were closed with advice and 3 registrants were issued a warning. Two cases were dismissed.

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 2014

Interim order hearings [private]

The Statutory Committee met on 12 occasions to consider interim order applications made by the Registrar. Three registrants appeared twice at the committee for review hearings.

One registrant was suspended by the High Court for 12 months, in 2014 having previously been subject to 3 interim suspension orders by the Statutory Committee totalling 18 months.

registrant	type	Order	date
A	Interim order hearing	Suspension	03/03/2014
B	Interim order hearing	None	03/03/2014
C	Interim order hearing	Suspension	28/04/2014
D	Interim order hearing	Suspension	28/04/2014
E	Interim order hearing	Suspension	29/05/2014
F	Interim order hearing	None	23/06/2014
G	Interim order hearing	Suspension	08/09/2014
H	Interim order hearing	Suspension	02/10/2014
D	Interim order hearing	Suspension	28/10/2014
G	Interim order hearing	Conditions	31/10/2014
E	Interim order hearing	Suspension	21/11/2014
I	Interim order hearing	Suspension	18/12/2014

Full conduct hearings [public]

The Statutory Committee met on 10 occasions in 2014 conducting full conduct public hearings.

Registrant	Date of hearing	Outcome
Case one	10/03/2014	Suspension
Case one	15/08/2014	Removal
Case two	26/03/2014	Adjourned
Case two	06/05/2014	Dismissed no jurisdiction
Case three	16/05/2014	Removal
Case four	13/06/2014	Conditions Order
Case four	22/09/2014	Suspension
Case five	16/06/2014	Removal
Case six	06/10/2014	Removal
Case seven	27/11/2014	Removal

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. Case details and associated 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 which were processed and these are outlined below:

a) Cases considered by the Statutory committee

Case One

The Statutory Committee inquired into the conduct and professional performance of a pharmacist considering allegations including:

- Instructing another pharmacist to supply a controlled drug in the absence of a valid prescription
- Not maintaining appropriate or contemporaneous records for supplies of prescription medicines
- Failure to maintain an accurate and contemporaneous record of the purchase and supply of a schedule 2 controlled drug Fentanyl.

Outcome 10/03/2014

The pharmacist did not engage with the FTP process but at a late stage referenced a possible health issue. The case was adjourned to allow any potential health issues to be explored.

Outcome 15/08/2014

The pharmacist did not engage with the FTP process and was removed by the committee due to a finding of impairment. See website.

Case Two

The Statutory Committee inquired into the conduct and professional performance of a registered pharmacy student [pre-registration trainee] considering allegations including:

- Theft of dihydrocodeine tablets from a registered pharmacy
- Theft of Zolpidem tablets from a registered pharmacy
- Obtaining employment and working as a pharmacist whilst not being registered

Outcome 26/03/2014

The registered student engaged with the process and was cooperative however the inquiry upon convening exposed a potential issue in regard to the jurisdiction of the committee to hear student registrant cases.
A registered student appeared not to be a ‘registered person’ as defined by the Order and therefore would not be subject to the authority of the committee.
The case was adjourned to allow the legal issues to be explored.

Outcome 06/05/2014

In reconvening the committee dismissed the case as they had determined that it had had no jurisdiction to hear this case. See website.

Case Three

The Statutory Committee inquired into the conduct and professional performance of a registered pharmacist considering allegations including:

- Theft of diazepam tablets from registered pharmacy premises
- Removal of diazepam tablets from registered pharmacy premises without an authorising prescription
- Convictions for theft in relation to the above matters.

Outcome

The registered pharmacist did not appear at the hearing or fully engage with the FTP processes**.** The registrant was removed by the committee having been found to be impaired. See website.

Case Four

The Statutory Committee inquired into the conduct and professional performance of a registered pharmacist considering allegations including:

- 13 convictions relating to the supply of Prescription Only Medicines which were not in accordance with an authorising prescription or without an authorising prescription.

Outcome 1 13/06/2014

The registered pharmacist was directed by the committee to commence a period of supervised training activity at a named pharmacy on a date and time appointed by the committee.

Outcome 2 22/09/2014

At the application of the registrar the registered pharmacist was investigated by the committee having then failed to commence the period of supervised training activity at the named pharmacy on the date and time appointed by the committee.
On hearing from the registrant the committee determined that the registrant was still impaired and suspended the registration of the pharmacist for a period of one year. See website.

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Case Five

The Statutory Committee inquired into the conduct and professional performance of a registered pharmacist considering allegations including:

- Supply of Prescription Only Medicines to at least 15 patients without the authority of an authorising prescription
- Supplies of medicines to a named patient without a prescription
- Dispensing Prescription Only Medicines, two antidepressants concurrently, to a single patient where one of these had been discontinued by the doctor and identified by the pharmacist.

Outcome

The registrant did not fully engage with the Committee and after investigation their fitness to practise was found to be impaired. The registrant was removed. See website.

Case Six

The Statutory Committee inquired into the conduct and professional performance of a registered pharmacist considering allegations including:

- Convictions on 5 counts relating to the making of indecent images of children
- Engaging in inappropriate and sexually explicit conversations with persons purporting to be 16 years of age or under.

Outcome

The registrant did not appear at the Committee hearing and after investigation their fitness to practise was found to be impaired. The registrant was removed See website.

Case Seven

The Statutory Committee inquired into the conduct and professional performance of a registered pharmacist considering allegations including:

- Excessive purchases of 'over the counter' medicines containing codeine
- Administering tramadol to themselves which was prescribed for another person
- Acquiring medicines from the pharmacy where they worked for the purposes of misuse or abuse
- Having traces of Prescription Only Medicines in a hair sample obtained by an employer whilst these medicines were not prescribed for them.

Outcome
The registrant did not appear at the Committee hearing but was represented. After investigation their fitness to practise was found to be impaired. The registrant was removed. See website.

Learning points

A. The pharmacist has a duty and function to maintain accurate and appropriate clinical and legal records of the supplies of medicinal products. The preparation and dispensing of medicinal products in anticipation of a prescription being supplied is not legal or good practice. It is considered to be best practice to make entries in a CD register contemporaneously on the date of dispensing the medication to the patient.

B. Engaging fully with the Scrutiny or Statutory committees may aid in the registrant's remediation and the committee when considering a registrants 'current' fitness to practise. The absence of this engagement will lead to a finding by a committee that only relates to past events and does not allow current status to be considered.

C. In relation to convictions obtained due to theft, these matters will be always be referred by the Registrar directly to a Statutory Committee in keeping with the FTP Regulations. This is an abuse of privilege and trust and will have a significant impact on damaging the reputation of the profession.

D. The practise of dispensing repeat medications or products solely from patient medication records (PMRs) in a pharmacy is inherent with risk. The pharmacy PMRs are useful adjuncts in the clinical care of the patient, however should not solely be referred to in the absence of a legally written and authorising prescription. There is no provision for the supply of medicinal products except on the authority of an authorising prescription or subject to the unique circumstances of an emergency supply at the request of a doctor or a patient. It is considered poor practice to make up medicines in advance of an authorising prescription. It is not legal to supply POMs in advance of a prescription unless this is an emergency supply and duly recorded as such.

E. In relation to therapeutic duplication of medicinal products on a prescription, it is the duty of a pharmacist to assess and challenge the prescriber if this occurs and where the patient is put at risk. A record of the communication with the physician should be made, preferably on the PMR, justifying any decision to continue supply where this is not logical.

F. In relation to convictions obtained due to the abuse of children or vulnerable adults, these matters will always be referred by the Registrar directly to the Statutory Committee. This is a serious abuse of trust and will have a significant impact on the victim as well as damaging the reputation of the profession.

G. In relation to the misuse or abuse of medicines by a registered person obtained due to theft, these matters will be referred by the Registrar directly to the Statutory Committee. This will require a health assessment in regard to the registered person and will also be considered as an abuse of privilege and trust having an impact which will damage the reputation of the profession.

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

Dispensing errors

There were five cases closed by the registrar in which the general issues were a dispensing error(s). In all cases the relevant common issue was the inaccurate final check made by each pharmacist before dispensing the medicine to the patient.
The patient received either:

- A lower dosage than that prescribed of the medicinal product
- The medicinal product which was not prescribed and unrelated to the clinical condition of the patient
- A medicinal product that was out of date

Furthermore there was an instance where prescriptions for two individual patients were combined in the surgery, [stapled together] subsequently this mistake was not identified in the pharmacy. As a result, a single patient received both therapies in error.

The final check of the dispensed product is the most important part of the dispensing process and when this is not completed correctly, errors occur. Near misses arise in dispensing practises but these should always be caught at the last step of the process, the final check. In all cases that were examined SOPs appeared to be adequate but were not followed to the letter by the pharmacist. Pharmacists should act to the letter of their own SOPs as these essentially define the quality assurance processes of the pharmacy in relation to the sale and supply of medicinal products.

Prescription collection and delivery

One issue arose over the continuity of supply and seamless care to a patient where the medications were not ordered by the pharmacy and consequently were then not available when needed by the patient.

The collection and delivery of patients own medicines including any arrangement for ordering the prescription medicines should always be consensual, transparent and timely, to avoid assumptions in providing the continuity of care either to the patient or by the pharmacist.

Personal honesty
Pharmacists are reminded that personal conduct in business or personal activities outside pharmacy practice will also impact on their current registration status with the Pharmaceutical Society of NI, as this may ultimately have an impact on the reputation of the profession.

14. The Pharmacy Network Group (PNG)

The Pharmaceutical Society NI, DHSSPS, BSO, and HSCB formalised a memorandum of understanding in 2009 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. These times are recorded from when a FTP complaint or concern is first identified to when the investigation is complete by the Registrar, the Scrutiny Committee or the Statutory Committee and subsequently closed.

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.

Registrars Investigations (13 weeks)
KPI indicator 1.1

Cases closed by Registrar	Initiation to date of closure by registrar[5]	7 cases
Average time to close	34	Weeks
Median time to closure	18	Weeks
Longest case	131	Weeks
Shortest case	11	Weeks
KPI closed <13 weeks of final report	2	29%

The target is to complete the investigation of the complaint/concern within 13 weeks. 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, the time to closure will increase as a result.
Two out of seven cases were closed in less than 13 weeks. The other cases involved obtaining a qualification of harm suffered from medical practitioners resulting in delays and the KPI not being met. Case times to closure in weeks were; 11, 13, 16, 18, 19, 28 &131.

Scrutiny Committee (26 weeks)
KPI indicator 1.2

Scrutiny Committee	From end of investigation to decision by Scrutiny Committee	9 cases
Average time to close	35	Weeks
Median time to closure	29	Weeks
Longest case	37	Weeks
Shortest case	13	Weeks
KPI closed <26weeks	3	33%

The target is to complete the investigation of the complaint/concern by a Scrutiny Committee within 26 weeks. 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 the time taken to closure will increase as a result.
Three out of nine cases were closed in less than 26 weeks. The other cases involved multi agency investigations which delayed the overall process resulting in failure to close these cases within 26 weeks. Case times to closure in weeks were 13, 17, 18, 27, 29, 37, 43, 43 & 89.

[5] Times quoted are from receipt of the complaint to the file closure

Statutory Committee (39 weeks)
KPI indicator 1.3

Statutory Committee	From date of referral by scrutiny to decision of Statutory Committee	6 cases
Average time to close	120	Weeks
Median time to closure	109	Weeks
Longest case	192	Weeks
Shortest case	78	Weeks
KPI closed <39 weeks	0	

The target is to complete the investigation of the complaint/concern by a Statutory Committee within 39 weeks. 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, the time taken to closure will increase as a result.
None of these cases were closed in less than 39 weeks. Four cases involved police criminal investigations and the remaining two related to components of health and conduct impairment. Two cases closed involved suspension for 12 months prior to removal and therefore the 52 weeks suspension time is reflected in the case closure times.
Case times to closure in weeks were 78, 80,102, 116, 150 &192.

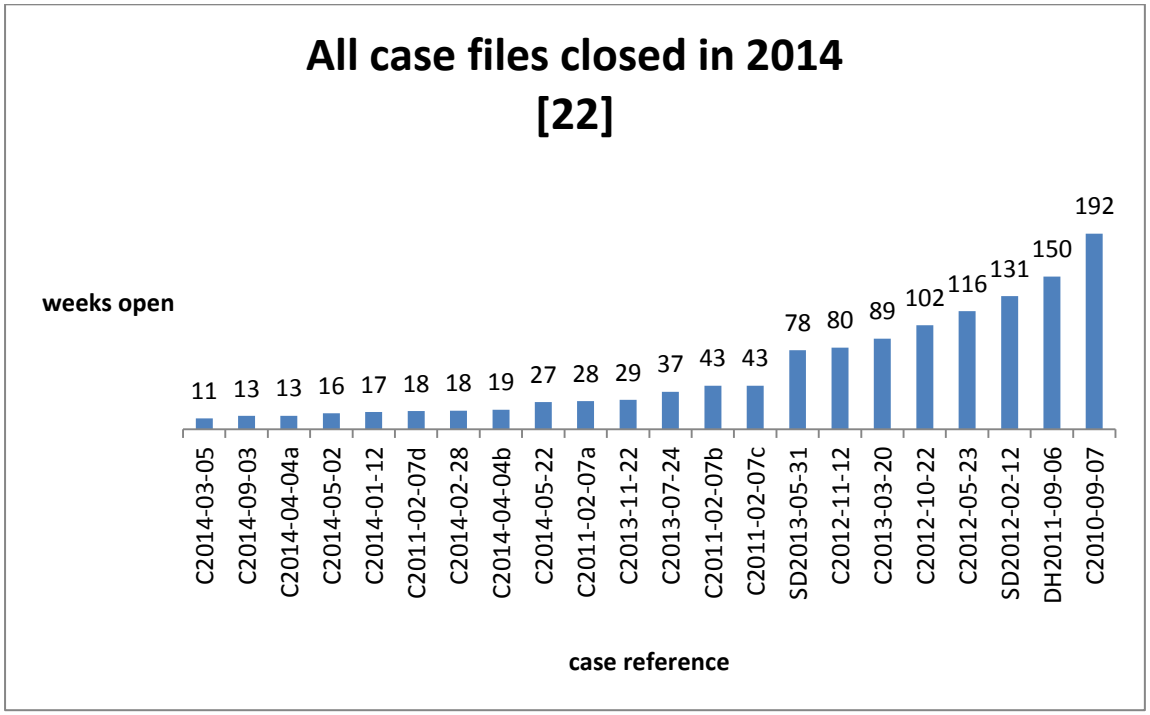
Summary of KPIs

	Internal KPI's					
	Factor	Weeks	Target	Total number	Met KPI	Percentage
	Case length					
1.1	Initiation to closure by Registrar	<13	90%	7	2	29%
1.2	Initiation to closure by Scrutiny Committee	<26	90%	9	3	33%
1.3	Initiation to closure by Statutory Committee	<39	90%	6	0	0
	Administration					
2.1	Complaint acknowledged	<5	100%	37	37	100%
2.2	Complaint is referred into pharmacy network group where significant	<5	100%	21	21	100%
2.3	Allocation of investigation external lead agreed	<3	95%	21	21	100%
2.4	End of investigation to consideration by a scrutiny committee	<9	90%	9	3	33%
2.5	Referral from Scrutiny to Statutory Committee	<9	90%	0	0	0
2.6	Complainant updated on mileposts	<13	90%	37	33	89%
2.7	Registrant updated on mileposts	<13	90%	37	33	89%
	Case files					
3.1	Closed cases reviewed	<9	100%	100		
3.2	Median, and mean reviewed by council ftp committee	6	meetings			
3.3	Open cases reviewed monthly	12	100%			
3.4	Median, and mean reviewed by council ftp committee	6	meetings			
	External investigations					
4.1	FTP committee updated wrt PNG activity on high risk, and or lengthy cases	6	meetings			
	Interim orders					
5.1	Conditions orders made	1				
5.2	Suspension orders made	9				
5.3	No order made	2				

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

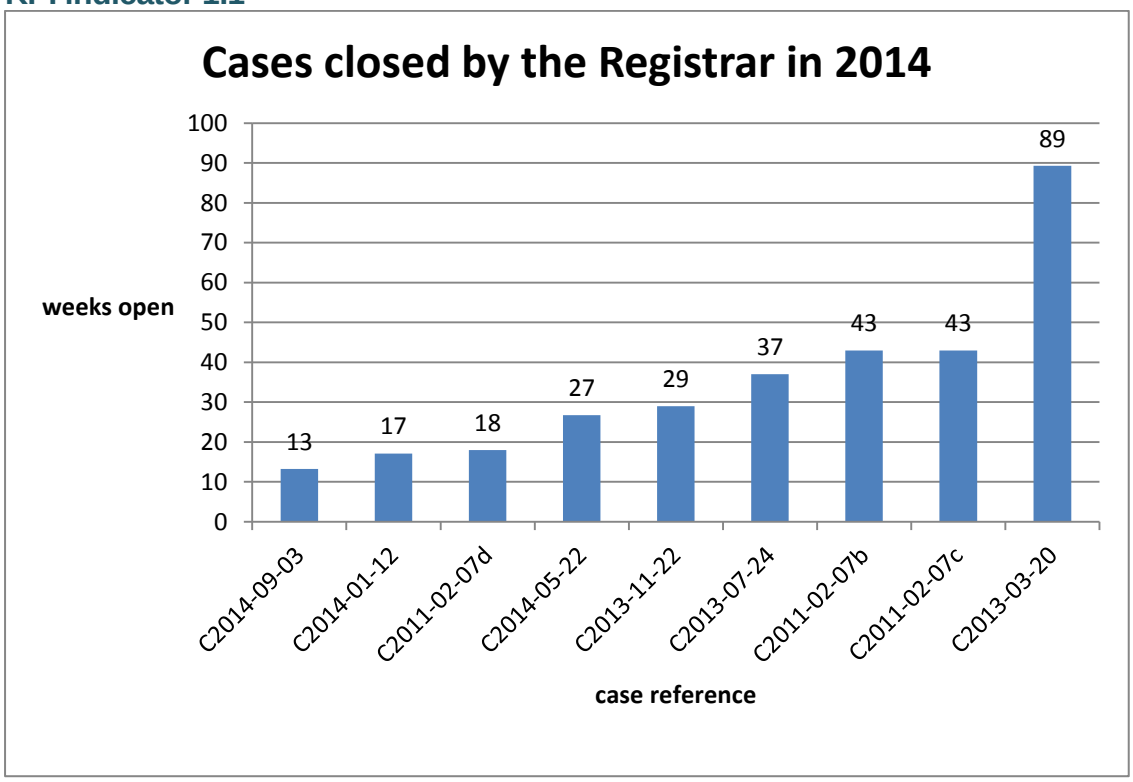
Closed cases

All case files closed in 2014 [22 cases]



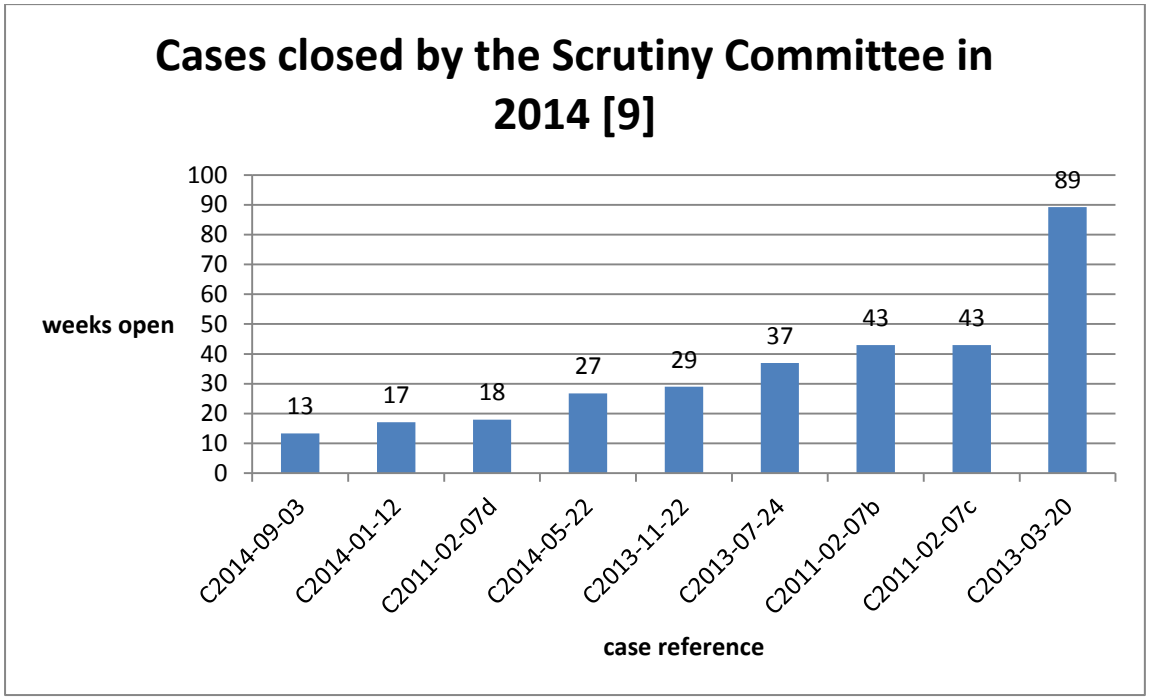
Cases closed by the Registrar in 2014 [7 cases]

KPI indicator 1.1



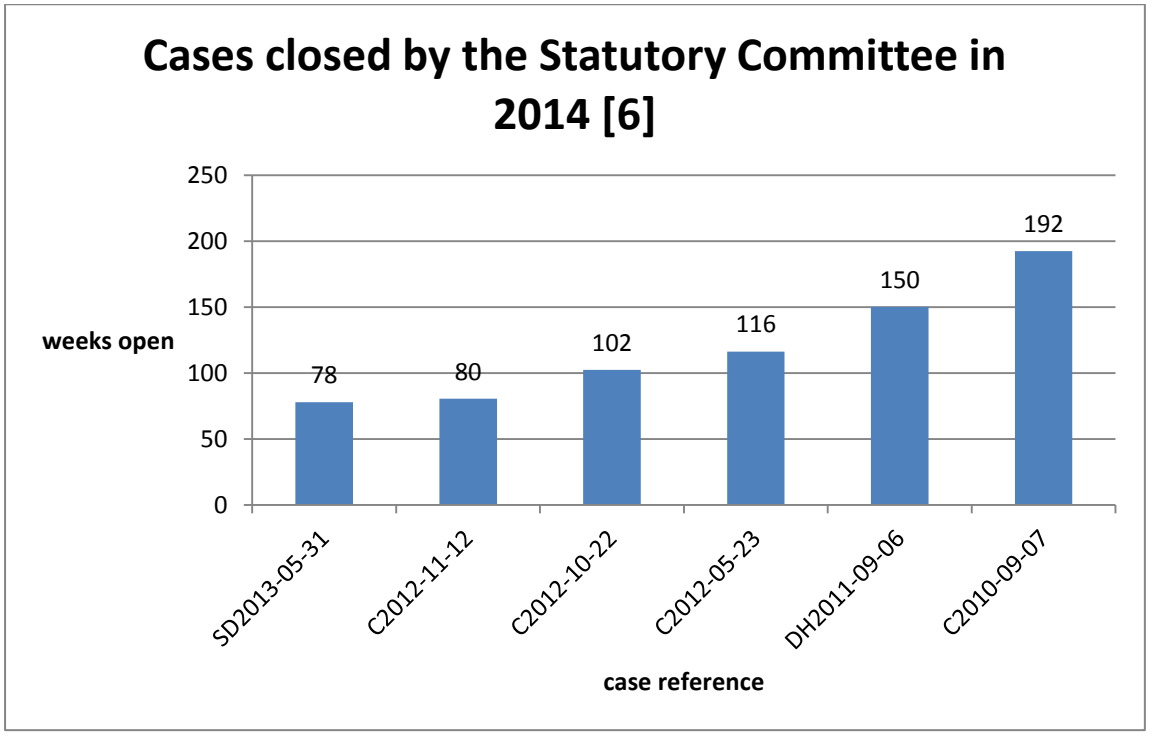
Cases closed by the Scrutiny Committee in 2014 [9 cases]

KPI indicator 1.2



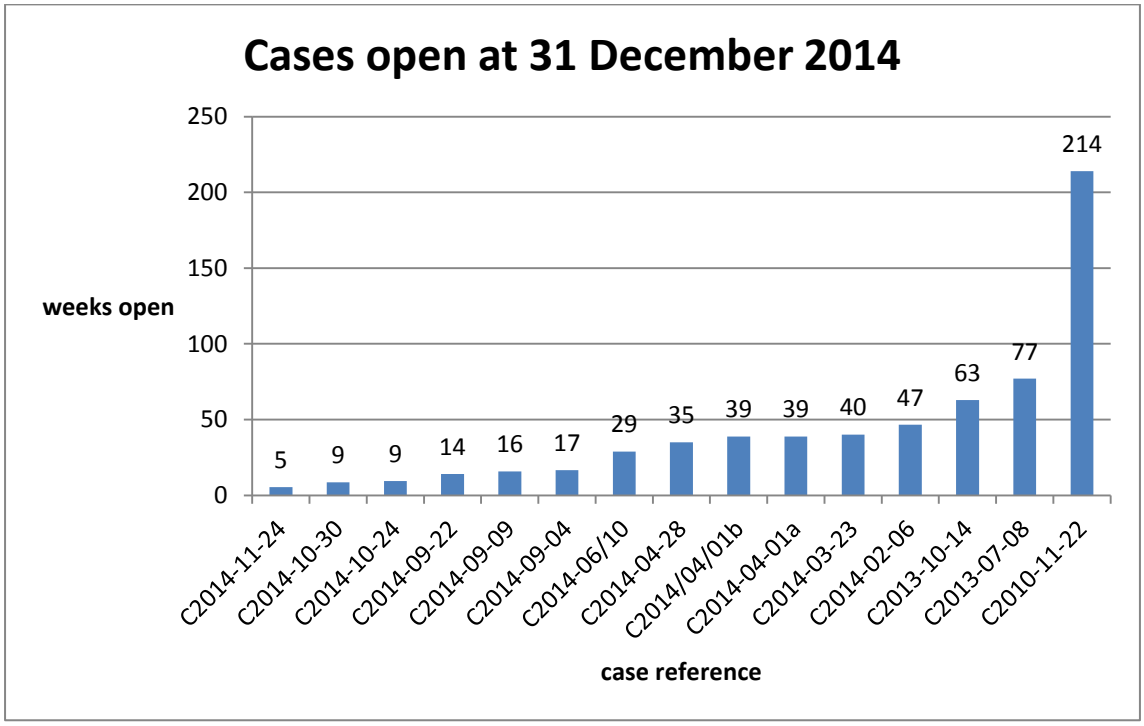
Cases closed by the Statutory Committee in 2014 [6 cases]

KPI indicator 1.3



Open cases

Case files remaining open on 31st December 2014



Appendix 1a Criteria for referral to a Scrutiny Committee [October 2012 to July 2014]

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 1b Criteria for referral to a Scrutiny Committee [July 2014 on]

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

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.
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.
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.
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.
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.
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.
7. Act with honesty, professionalism 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.
   c. There is evidence that the registered person failed to demonstrate high standards of personal and professional conduct.

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 2014

Statutory Committee
2014

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

Appendix 3 Scrutiny Committee Annual report 2014

Annual Report of the Scrutiny Committee 2014
One of the obligations of the new legislation introduced in 2012 was the provision by the Scrutiny Committee to the Council of the Society, 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 second such report and covers the calendar year of 2014. 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 (resigned in June 2014)
Lay member	Mr. Colin Kennedy (appointed July 2014)
Pharmacist member	Mrs. Bronagh White
Pharmacist member	Prof. Colin Adair
Pharmacist member	Mr. James Taggart

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 Society 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, 2014
The committee sat on five occasions dealing with a total of eight cases, in the full calendar year. A short summary of those cases is attached hereto at Appendix one, detailing the registrant, the date of meeting, 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 two 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 eight 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 none of this year's cases did the Scrutiny Committee conclude that the threshold for referral on to the Statutory Committee had been met. In each of the 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). The Committee suspect that, having dealt with a backlog of more serious cases last year, the profile of cases this year was slightly unusual, in not having any cases that required to be forwarded on to the Statutory Committee.

The statutory purpose of this report:
Regulation 7(1) a(i) : "Trends, Patterns and Learning Points"

As required by the legislation mentioned earlier, the first purpose of this report is to identify "trends, patterns and learning points" and bring these to the attention of the

Council of the Society, 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 many of the cases referred to it, this year, involved dispensing errors of varying degrees. The particular trends and or patterns of behaviour that came to the attention of the Committee often involved the interplay between human error and SOPs. This would seem to be a perennial problem, and the comments below will no doubt require the Council of the Society to reiterate advice to the profession on such issues.
There was also one case involving "drink driving". 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 are a summary of the points made by committee members, as to what could be considered learning points, which were considered and gathered from the panel members at the end of each meeting, on the dates given. 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 points for the profession – recorded at Scrutiny Committee meetings in 2014

<u>Meeting date; 09-04-2014</u>

- Resources available for the design of pharmacy SOPs should be seen only as a template for local implementation and not a document for immediate use. SOPs should be tailored to fit the needs of the business and skill set of the staff in that particular business;
- Medicinal products with similar names should be highlighted and stored separately where possible to reduce the risk of 'picking errors'.

<u>Meeting date 13-05-2014</u>

In cases where there has been a conviction for drink-driving, registrants can expect to be referred to the Statutory Committee unless the following factors apply:

i. It's a first offence;
ii. There are no apparent aggravating factors e.g. harm to others; excessive levels of alcohol in breath or in blood etc;
iii. There is a level of insight exhibited by the registrant;
iv. Medical evidence does not highlight alcohol issue.

- Profession should be fully aware that they have a legal requirement to report any fitness to practise matters within 7 days of the date of occurrence to the regulator;

- Where relevant healthcare professionals are required to co-operate with health assessments were there are issues of potential impairment.

Meeting date 13-06-2014

- The Committee highlighted inherent flaws in the MDS system that placed undue pressure on pharmacists to meet timelines and highlighted issues with regard to responsibilities for delivery to the patients;
- The Committee highlighted accountability for staffing issues leading to unsafe working environments within multiple pharmacy companies lies with the SI and therefore should be addressed by the SI.

Meeting date 25-11-2014

- Pharmacists should monitor workloads and ensure that there is appropriate staff present to cope with increased workload. Patient safety is paramount;
- SOPs should constantly be under review to ensure that drugs with a high rate and risk of dispensing errors are handled with care;
- Care should be taken to ensure that labelling regulations are adhered to.

Meeting date 05-12-2014

- Pharmacists should constantly review SOPs and where deficiencies are identified, should make recommendations for change;
- Stress the importance of a final check, and counselling of a patient on each occasion of dispensing a medication;
- Important not to over rely on technology to select appropriate products, pharmacists should use their own initiative to perform a final check;
- Profession should note that Scrutiny Committee can issue advice to employers/Superintendents if deficiencies in systems are identified.

Regulation 7(1) a (ii): "Details of disposals by warnings and undertakings"
As required by the legislation mentioned earlier, the second purpose 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 Society. The purpose of this part of the annual report is to inform the Council of the Society of the detail of such cases. There were eight such cases, four of which resulted in advice about future conduct being given, whilst three cases resulted in a formal warning. One case was dismissed. These cases are identified in the report at appendix one hereto.
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 eight 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 Society that the Scrutiny Committee is exercising its powers in an appropriate way. For example, if the Council of the Society 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 six of the cases disposed of by way of advice or warning fell into the category of case which might be described as “dispensing error”. The other case was 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 had dispensed to Patient A, Amlodipine 10 mg (56) in error and not Amitriptyline 10 MG (56) tablets as prescribed, and accordingly as a result of the dispensing error Patient A suffered moderate harm. It was alleged that there was evidence that the registered person’s conduct or performance caused moderate harm, which could and should have been avoided and that there was 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. The allegation was admitted. The Committee was of the opinion that this was an appropriate case to exercise its power to issue advice. The Committee considered the following relevant factors:
That the person concerned had taken full responsibility for the error which had been the result of a ‘picking error’ that she had failed to detect at the checking phase

- That this was a single one-off dispensing error and that the person concerned had practised as a pharmacist for over 25 years with an unblemished record prior to this incident;
- That subsequent to the incident the person concerned had successfully completed the NICPLD on-line course on ‘Improving Patient Safety’. This included 1) separating and highlighting drugs with similar names; 2) ensuring she is satisfied with her work environment, that is that she has adequate time and space to accurately check a prescription; 3) ensuring her workload is varied and not repetitive; 4) ensuring the correct placing of labels on medicine containers; 5) endeavouring to counsel patients as much as possible; and 6) double-checking prescriptions before they are transferred to patients.

Registrant B.
In this matter the registrant faced the following allegations:-

(i) On 18 October 2013 at the Laganside Magistrates Court the person concerned was convicted of the following offence:

(a) Driving with excess alcohol in breath.

(ii) That the person concerned failed to notify the registrar in writing, within a period of 7 days, of the aforesaid conviction, as required by Regulation 3(1) of the FTP Regulations 2012.

It was alleged that there was evidence of behaviour on the part of the person concerned which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body. The allegation was admitted. The Committee was of the opinion that this was an appropriate case to exercise its power to issue a warning. The Committee considered that the public perception of drink-driving, was that it was socially unacceptable and should be considered as a serious matter in every case and particularly so, when it involved a healthcare professional who ascribed to a level and standard of behaviour befitting the profession to which they belong. They considered the following mitigating factors:

- The offence itself was a first offence and lacked any aggravating factors, such as an exceptional high level of drunkenness, or a road traffic collision that might have caused physical injury to either the person concerned or a third party. The person concerned received the minimum penalty (12 months disqualification) and this was further reduced upon successful completion of a driving course. Without in any way minimising the seriousness of such offences, in terms of the scale of drink driving offences, it could be categorised as being at the “bottom of the scale”;

- The Committee noted the medical evidence, which supported the submission that there was no underlying alcohol problem which may have raised concerns as to the possible re-occurrence of such behaviour;

- The Committee also was impressed by the honesty and insight displayed by the person concerned, in the manner in which she accepted the seriousness of the matter and also how she engaged and cooperated with the Society. For these further reasons the Committee, considered that it was very unlikely that there would be a re-occurrence of this type of behaviour;

- The Committee further noted that the registrant had submitted character references one of which was from her employer whom she had made aware of the incident. The Committee felt this demonstrated further insight and that she had taken responsibility for her actions;

- The Committee accepted the registrant’s explanation for not reporting the incident as set out in the regulation 3(1) and in regulation 3(2)], within the period of 7 days.

The Committee wish to make it clear that if any of these factors had been absent or if there had been any aggravating factors to the facts of the offence, it would have been unable to conclude that the case was capable of being disposed of without reference to the Statutory Committee. The published GMC guidance notes as follows:

“Examples of convictions and cautions that have resulted in a warning include one off drink driving offences where we are satisfied that there are no underlying health concerns”.
The Committee concluded that this case fell into that description and there were no compelling reasons to treat the matter in a different way.

Registrant C.
In this matter the registrant had:

- Incorrectly dispensed and supplied a prescription drug, namely Plaquenil 200 mg to Patient A in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that she supplied the said drug instead of Priadel 200 mg which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;
- Incorrectly dispensed and supplied a prescription drug 14 Zopiclone 7.5 mg tablets to Patient B in circumstances corresponding to a retail sale in contravention of Section 58 (2) of the Medicines Act 1968 in that she supplied the said drug instead of Zopiclone 3.75 mg tablets which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;
- Incorrectly dispensed and supplied a prescription drug, namely Omeprazole 20mg to Patient C in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that she supplied the said drug instead of Omeprazole 10 mg which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;
- Incorrectly dispensed and supplied a prescription drug, namely Trimethoprim 200 mg to Patent D in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that she supplied the said drug instead of Trimethoprim 100 mg which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;
- Incorrectly dispensed and supplied a prescription drug, namely Temazepam 10 mg x 27 tablets to Patent E in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that she supplied the said drug instead of Temazepam 10 mg x 28 tablets which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;
- Incorrectly dispensed and supplied a prescription drug, namely Metformin 100 ml to Patent F in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that she supplied the said drug instead of Metformin 150ml which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;

It was alleged that there was evidence that the registered person’s conduct or performance was reckless and that the registered person has practised in a way that was systematically unsafe, or, has allowed or encouraged others to do so, and had put patient safety at risk. The allegations were admitted. The Committee was of the opinion that this was an appropriate case to exercise its power to issue advice. The

Committee considered this case involving dispensing errors; however it was not the number of errors that troubled the Committee. Rather it was the nature of the errors that occurred that was the important factor. Single dispensing errors, which do not involve harm to the public, rarely trouble the Committee. Multiple dispensing errors may rightly lead to a query over the fitness to practice of a registrant. Each case will be very fact specific. In this case, when considering the allegations, which occurred over a relatively short period of time, the Committee took into account the mitigating factors set out in detail by the solicitors acting for the person concerned. The Committee accepted that the following factors were particularly relevant:

- The Committee were impressed by the honesty and integrity exhibited by the person concerned highlighted in the prompt , accurate and concise manner in which the incidents were reported;
- The Committee noted the appropriate action had been taken to the reduce the risk of any future incidents of this nature occurring, and that the person concerned had taken action to mitigate the risk to patients;
- The Committee noted that there was no evidence of any patient harm as a result of these incidents;
- The Committee noted the significant pressure the person concerned had endured due to staff shortages within the pharmacy at the time when a number of these incidents occurred;
- The Committee noted the level of insight and diligence demonstrated by the person concerned in that she had undertaken further Continuing Professional Development as a result of these incidents and had engaged fully in the process;
- The Committee noted the wide range of testimonials submitted on behalf of the person concerned who describe her as a caring and conscientious pharmacist.

<u>Registrant D.</u>

In this matter the registrant had:

- Incorrectly dispensed and supplied a prescription drug, namely 28 Co-beneldopa 250mg to Patient X in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that he supplied the said drug instead of 28 Co-beneldopa 125mg which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;

- Incorrectly dispensed and supplied a prescription drug, namely Bicalutamide 150mg daily for a period of 19 weeks to Patent Y in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that he supplied the said drug instead of Bicalutamide 50mg daily which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968;
- Incorrectly dispensed and supplied a prescription drug, namely Insulated Innolet 100 units/ml to Patent Z in circumstances corresponding to a retail sale in contravention of Section 58 (2) (a) of the Medicines Act 1968 in that he supplied the said drug instead of Levemir Innolet 100 units/ml which should have been supplied in accordance with the corresponding prescription contrary to Section 67 (2) of the Medicines Act 1968.

It was alleged that there was evidence that the registered person's conduct or performance was reckless and that the registered person has practised in a way that was systematically unsafe, or, has allowed or encouraged others to do so, and had put patient safety at risk. The allegations were admitted. The Committee was of the opinion that this was an appropriate case to exercise its power to issue advice. When considering the allegations, which were spread over the course of approximately one year, the Committee felt that there was no evidence of a pattern of conduct developing that would have concerned the Committee. These appeared to be three isolated incidents. It was noted by the Committee the potential for risk to the patient on the supply of the incorrect insulin had it not been identified by staff on receipt of the supply of the medicine at the nursing home and was reported appropriately as a "near miss."
The Committee then took into account the mitigating factors set out in detail by the solicitors acting for the person concerned. The Committee accepted that the following factors were particularly relevant:

- The Committee noted that the person concerned had made full admissions with regard to these incidents and had reported them, albeit noting that, with regard to the incident occurring on 24th August 2012, this incident had not been reported until 18th October 2012;
- The Committee noted that appropriate action had been taken to the reduce the risk of any future incidents of this nature occurring, and that the person concerned had taken action to mitigate the risk to patients;
- The Committee noted the significant pressure the person concerned had endured due to staff shortages within the pharmacy at the time that a number of these incidents occurred;
- The Committee noted that insight had been shown by the person concerned in that he had undertaken further Continuing Professional Development as a result of these incidents and had engaged fully in the process.

<u>Registrant E.</u>
In this matter the registrant had:

- Dispensed Atenolol 100mg in circumstances corresponding to a retail sale in contravention of Section 64(1) of the Medicines Act 1968, in that you supplied a medicinal product which was not of the nature or quality demanded by the patient or in accordance with the presented prescription contrary to Section 58(2)(a) of the Medicines Act 1968;
- That on or about 22 May 2013 you dispensed a medicinal product in contravention of section 258 of The Human Medicines Regulations 2012 insofar as you did not satisfy the packaging requirements laid down in Schedule 25 Part 1 of The Human Medicines Regulations 2012.

It was alleged that there was 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, and that the registered person's conduct or performance was reckless in that the registered person has practised in a way that was systematically unsafe, or, has allowed or encouraged others to do so, and had put patient safety at risk.

The factual matrix in this case was that the patient received one tablet of the drug Atenolol, a beta blocker, when she should have been given Allopurinol. The patient was 85 years old and in poor health, with a history of heart failure. On the next morning and after taking the tablet, she collapsed and later died. It appears to have been presumed that her death was in some way caused or contributed to, by taking the Atenolol tablet. However, this was not borne out by the evidence.
The allegations were admitted. The Committee made it quite clear that they saw no link between the two events and therefore the assessment of this case must be made on the basis that this was a single dispensing error which resulted in no harm being caused to the patient. The Committee was of the opinion that this was an appropriate case to exercise its power to issue a warning. Against the background of no harm being caused, the Committee were impressed by the following mitigating factors;-

- The lengthy unblemished career of the registrant (28 years);
- The seriousness with which both she and her employer responded to the incident;
- The insight demonstrated by the Registrant, (the Committee were satisfied that the likelihood of a repeat of such a mistake was remote in the extreme);
- The careful and considered way in which the registrant (with the help of her employer) slowly returned to employment, built up her confidence, and worked on amending the SOP's to ensure a repeat could not occur;
- The fact that she was trying to be helpful to ensure the patient received their medication;
- The testimonials from her colleagues.

Registrant F.
In this matter the registrant had been responsible for dispensing medication without a prescription to a Patient in circumstances corresponding to a retail sale in contravention of Section 64(1) of the Medicines Act 1968, in that he supplied a medicinal product which was not of the nature or quality demanded by the patient. Namely, he dispensed Movicol rather than Movicol Paediatric.
The factual matrix in this case was that the allegation (as set out above) had been made against the registrant in very vague terms, to the extent that the Committee agreed to dismiss it, for lack of sufficient evidence. However in the course of the investigation the registrant volunteered that he had been responsible for a similar error to the one alleged, albeit on a different date.
The person concerned was to be commended for volunteering this information. However the inescapable conclusion was that, what was described and admitted to, amounted to, not just a picking error, but potentially dispensing without a prescription (albeit as an emergency supply).
The Committee felt that having dismissed the actual charges, but having received admissions in relation to such similar charges, the most practical method in resolving the referral, was to provide advice to the person concerned, to provide an indication that such conduct could not be condoned by the Committee.
Registrant G.
In this matter, the registrant:-

- Had (on more than one occasion) dispensed a prescription in circumstances corresponding to a retail sale in contravention of Section 64(1) of the Medicines Act 1968, in that you supplied a medicinal product which was not of the nature or quality demanded by the patient. Namely, he dispensed Ranitidine Oral Solution

150mg/ 10 ml 4 ml qid instead of Ranitidine Oral Solution 5mg/ 5 ml 4 ml tid to Patient A;

- Was responsible for the dispensing of a prescription in circumstances corresponding to a retail sale in contravention of Section 64(1) of the Medicines Act 1968, in that under his authority a medicinal product was supplied which was not of the nature or quality demanded by the patient. Namely, he dispensed a box of 56 Naproxen 250mg tablets instead of a box of 56 Naproxen 500mg tablets to Patient B;
- Was the Responsible Pharmacist on duty at the time of the dispensing errors outlined above and the incorrect labelling outlined at paragraph (iv) relating to Patients A and B and thereby breached his duty under Section 72A(1) of the Medicines Act 1968 in that he failed to secure the safe and effective running of the pharmacy business at the premises in question so far as concerns the retail sale at those premises of medicinal products and the supply at those premises of such products in circumstances corresponding to retail sale.

It was alleged that there was 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, and that the registered person's conduct or performance was reckless in that the registered person has practised in a way that was systematically unsafe, or, has allowed or encouraged others to do so, and had put patient safety at risk.

In this case the Committee have found that the person concerned has made multiple dispensing errors in a relatively short period of time. It is the repetition of error that causes the Committee to be sufficiently concerned about the conduct and fitness to practice of the person concerned, to justify issuing a warning. The following factors were relevant:

- An adult dose of Ranitidine was dispensed to a vulnerable child and the Committee felt insufficient care was taken when checking the prescription for accuracy and clinical appropriateness especially when considering the age of a patient and ensuring the appropriateness of the dose prescribed;
- The error in relation to the vulnerable child occurred on 4 separate occasions before it was discovered;
- Given that the dosage prescribed required to be measured accurately using an oral syringe there appeared to be a lack of appropriate advice given to the child's mother on the appropriate measurement of the prescribed dose;
- The error in relation to Naproxen occurred a short time after the errors in relation to Ranitidine which indicated that limited and insufficient learning had been taken from the earlier mistakes;
- The person concerned did not appear to respond to the investigation by the Society in manner which demonstrated a high level of insight into the potential seriousness of the matters;
- Despite the Committee seeing obvious deficiencies in the SOPs, that may prevent the repetition of these types of errors, the person concerned has not demonstrated efforts to seek that these be amended.

In mitigation, the Committee took into account the submissions made by the person concerned along with the testimonials that he provided and his previously unblemished record over 30 years.

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 Society 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 Society, 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)
20 February 2015

Appendix 4 Meetings of the Scrutiny Committee 2014

Date of meeting	Chair	Lay member	Pharmacist member	Disposal
09/04/2014	Rosemary Connolly	Andrew Thomson	James Taggart	Advice
13/05/2014	John Gibbons	Jinna Brownlees	Bronagh White	Warning
13/06/2014	John Gibbons	Jinna Brownlees	Bronagh White	Advice
13/06/2014	John Gibbons	Jinna Brownlees	Bronagh White	Advice
25/11/2014	John Gibbons	Andrew Thomson	Colin Adair	Warning
05/12/2014	John Gibbons	Andrew Thomson	Bronagh White	Case Dismissed
05/12/2014	John Gibbons	Andrew Thomson	Bronagh White	Advice
05/12/2014	John Gibbons	Andrew Thomson	Bronagh White	Warning

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.

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