
Fitness to Practise Report 2009

Including learning points for pharmacists

Pharmaceutical
Society
of
Northern Ireland

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Introduction

The Pharmaceutical Society of Northern Ireland 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.

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

The Pharmaceutical Society of Northern Ireland has on its registers 2060 pharmacists and 542 pharmacy premises. All pharmacists are regarded as practising and there is no provision for a non practising register of pharmacists. Currently the Pharmaceutical Society does not register pharmacy technicians as there is no statutory legislation to underpin this. Details of registered pharmacists can be found on the web based register [Search the Register](#) or by phoning the offices during working hours 9am to 5pm Monday to Friday 02890326927.

The report is based on a calendar year 2009 but will include cases carried over from the previous year. The Pharmaceutical Society of Northern Ireland does not employ its own inspectors but utilises the pharmaceutical inspectorate of the DHSSPSNI 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 potential breaches of the PSNI Code of Ethics and Standards and Guidance. The Pharmaceutical Society of Northern Ireland also works closely with officials of the Health and Social Care Board and Business Services Organisation.

2008 cases

In 2009 eleven case files relating to complaints concerns or incidents regarding pharmacy practise were carried over from 2008.

Closed cases

Seven of these cases were then concluded in 2009.

- 2 cases were reviewed by the Registrar with reference to threshold criteria and this resulted in no further action.
- 2 cases involved medication dispensing errors which were then examined by the Scrutiny Committee and post examination, and, with reference to threshold criteria were not referred to the Statutory Committee as there was no likely probability that the case would result in the pharmacist being removed by the Statutory Committee.

- 3 cases were examined by the Scrutiny Committee and then referred on for investigation by the Statutory Committee. See report of Statutory Committee.

Open cases

Four cases are still active from 2008.

- One health case.
- Three cases requiring further investigations by DHSSPS, HSCB or Counter Fraud Unit.

Origins of cases

The 12 case files initiated in 2008 were sourced as follows:

- 3 cases initiated with the DHSSPS, HSCB or RQIA.
- 5 cases were initiated directly with the PSNI.
- 1 was a whistleblowing concern raised with the PSNI.
- 1 was a self declared health related issue.
- 2 were self declarations related to conduct, convictions or pending hearings.

2009 cases

In 2009 there were 59 case files opened in relation to complaints concerns or incidents related to pharmacy practise or medicines.

Closed cases

In 2009 there were 35 case files closed relating to complaints concerns or incidents in 2009.

- 2 health cases.
- 3 cases related to driving convictions.
- 2 related to student conduct offences.
- 18 were related to medicines issues.
 - 5 related to the supply of prescription medicines by a pharmacy without prescriptions being evident.
 - 5 related to issues of packaging or labelling of medicines.
 - 2 related to owing medications.
 - 2 related to dispensing errors.
 - 2 related to CD entries in the pharmacy.
 - 1 related to supermarket medicine supply.
 - 1 related to the sale or supply of a nostrum or pharmacy prepared medicine

Open cases

There are 34 cases which are currently open relating to complaints, concerns or incidents involving pharmacy or medicines.

Of these cases

- 24 remain under investigation by the DHSSPS or HSCB.
- 2 await results of pending legal proceedings. Notification was made by self declaration
- 1 is subject to health proceedings.
- 5 are in preparation for presentation to the Scrutiny Committee.
- 2 are under currently under review by the Registrar.

Types of case under investigation

32 cases under investigation relate to the sale supply or records associated with medicines. Two cases relate to the activities of persons alleged to have worked as a pharmacist whilst not being registered.

Origins of cases

The 59 case files initiated in 2009 were sourced as follows

- 26 cases initiated with the DHSSPS OR HSCB, RQIA.
- 19 cases were complaints addressed directly with the PSNI.
- 4 were concerns raised with the PSNI seeking clarification on professional conduct issues
- 3 were health related issues self declared.
- 7 were self declarations related to conduct convictions or hearings.

Scrutiny Committee

The Scrutiny Committee was constituted in 2009 as an advisory committee to the Registrar in relation to fitness to practise matters. This has no statutory function but is an advisory committee. All members of the committee have completed the same fitness to practise [FTP] training as the members of the Statutory Committee and are aware of the current issues in FTP. The committee meets to review paper based evidence where neither the complainant nor registrant is present. Its role is to advise the Registrar whether, on the basis of the available evidence, there is a case to answer which could result in erasure from the register, and therefore merits referral to the Statutory Committee for a hearing.

Membership of the committee

Dr Denis Morrison [pharmacist], Mr Conor Heaney [lay] and Mrs Maureen Brennan [lay].

Meetings of the committee

The committee met on six occasions in 2009 and reviewed ten case files. The committee applies threshold criteria to each case and then recommends where appropriate further referral.

Committees recommendation to the Registrar

- Three cases were recommended for referral to the Statutory Committee.
- Three cases were considered in relation to driving offences and were not recommended for further referral.
- Two cases were considered in relation to conduct whilst being a student and the individuals were now seeking admission to pre-registration training and student registration neither case was recommended for further referral.
- Two cases were considered in relation to single medication [POM] dispensing errors and were not recommended for further referred.

Statutory Committee

The Statutory Committee is constituted under the Pharmacy (Northern Ireland) Order 1976 and Pharmacy Order Regulations 1947. The Chair is appointed by the DHSSPS and the members appointed by the Council have been recruited through an independent public appointments process since 2008.

Membership of the Committee

Mr Tim Ferriss QC [Legally qualified chair], Mr Roy Junkin [lay], Mr Andrew Thomson [lay], and Ms Miriam Karp [lay] Dr Terry Maguire [pharmacist] and Mrs Hilary Rea [pharmacist].

Meetings of the Committee

The Committee held hearings on three occasions. The Committee also met for one training event and one business related meeting.

1. Inquiry into Mr Stephen Twibill registration number 2227

An inquiry was held on 17th June 2009 regarding convictions handed to Mr Twibill in November 2008 in contravention of Article 3(1)(a) of the Protection of Children (Northern Ireland) Order 1978.

Mr Twibill was represented at the hearing and the Committee determined after inquiry to remove Mr Twibill from the register, also indicating he should not be considered for restoration for a period of 15 years.

On 9th September 2009 Mr Twibill served notice of his appeal against this outcome, to the High Court in Northern Ireland. This matter is awaiting hearing by the High Court and Mr. Twibill's name remains on the register of pharmacists.

2. Inquiry into Mr Martin Joseph McDaid registration number 2846, Mr Michael John Joseph McDaid registration number 3302 and M & M McDaid Limited

An inquiry was held on 24th and 25th June and 1st July 2009 regarding convictions handed to M & M McDaid Limited. On 8th December 2008 M & M McDaid Ltd, of which Mr Martin Joseph Patrick McDaid and Mr Michael John Joseph McDaid were Directors, pleaded guilty to and was convicted of nine offences in contravention section 17(1)(a) of the Theft Act (Northern Ireland) 1969,

Both Mr McDaid's and the Company were represented at the hearing and the Committee determined after inquiry to remove Martin Joseph Patrick McDaid and Mr Michael John Joseph McDaid from the register also indicating they should not be considered for restoration for a period of 5 and 7 years respectively. No action was taken with regard to the company M & M McDaid Limited.

As neither person appealed this determination both individuals were removed from the register on 2nd October 2009.

3. Inquiry into Mr Parimal Bavalia, registration number 1982.

An inquiry was held on 24th July 2009 with regard to alleged misconduct. It was alleged that on 30th September 2008 whilst working as the pharmacist in his pharmacy at Newtownabbey, that in contravention of Section 58 of the Medicines Act 1968 he dispensed a medicinal product other than in accordance with a prescription causing, allowing or permitting a patient to be dispensed with the wrong medicine.

Mr Bavalia was represented at the hearing and the Committee decided after inquiry that the misconduct did not merit removal from the register.

Learning points

1. Statutory Committee cases

Michael and Martin McDaid's

Medicines dispensed on prescriptions should in all cases be labelled with the requirements of the Medicines Labelling Regulations 1976. No extra details should be added which would lead to misinterpretation or confusion by the patient or payment authority. Vigilance should be exercised in auditing prescriptions sent for payment to the pricing authority to ensure appropriate payment claims are made.

Parimal Bavalia

The action of a dispensing error brought into focus the inadequacies of the pharmacy's standard operating procedures, SOPs. Although these were present they were not adhered to nor were they personalised to the individual practice of the pharmacy. This has since been addressed by the practitioner.

The need for SOPs is now a legal requirement under the Responsible Pharmacist Regulations. This provides a quality framework for the public and the pharmacist in the provision of pharmaceutical care. The Chair of the Statutory Committee has noted in summary that the production and use of SOPs is required to be evidenced in any case which comes before the Committee.

2. General case files not referred to Statutory Committee inquiry.

Dispensing errors

Where a pharmacist has been involved in a dispensing error he/she must always put the interests of the patient first. It is required that the practitioner.

- Immediately addresses the issue.
- Apologises to the patient/carer.
- Checks on the health status of the patient, 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.
- Supplies the correct medication to the patient.
- It is considered to be good practise to inform the patients Doctor of the incident to maintain the quality of their healthcare.
- Records contemporaneously the incident in a critical incident log.
- Conducts a full root cause analysis of what happened and why.
- Reviews SOPS to identify any changes that are required to be made and actions this.
- Identifies any other issues requiring attention e.g.
 - Information technology
 - Human resources [staffing quotas]
 - Training needs
- Reports on the incident to the patient
- Reports on the incident to the superintendent or owner
- Actions any remedial issues identified above

Where these guidelines are followed there is opportunity for learning and *fair blame*. Patient confidence is often maintained by the methodology used. There are some 30 million prescription items dispensed in Northern Ireland each year. Reported dispensing errors number less than 100. The accuracy rates are extremely high but this is not leave room for any complacency and a single error can cause great harm or death to a person.

The function of fitness to practise processes is not to punish a pharmacist but to 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.

Owing of medicines

Complaints often arise where a pharmacist has given an incomplete supply of medicines to a patient and the patient then is unable to obtain the outstanding balance. Care needs to be observed in relation to interrupting the patient's treatment regime. The patient should always be given a written form of notation identifying the outstanding medication(s) and if appropriate a timeframe for the supply to be completed¹. Where medicines are in short supply the pharmacist should contact the surgery to identify the issue and arrange a suitable alternative. The prescription payment body, BSO, should be notified of any under supply and payment amended to reflect the shortfall.

Nostrums and medicines made on the request of a patient

There have been well publicised cases of medicines being compounded by pharmacists which breach the requirements for labelling or legal supply.

Diluting a prescription only medicine does not usually make it suitable for sale. Pharmacists are reminded of the legal requirements for extemporaneous medications¹ and should make appropriate records of the constitution, stability, storage requirements and expiry of these medications.

Good practise requires that patient names are recorded in the pharmacy record for specials. The patient name should always be on the label. Pharmacists should pay particular attention to paediatric medicines which will relate to age and body weight of the patient.

Emergency supply of medicines which are prescription only

Pharmacists are reminded of the recent changes in the emergency supply of medications [emergency supply](#). These can be at the request of a patient or doctor. If a doctor has requested the supply then a prescription must be furnished within 72 hours. If the supply is at the request of a patient the pharmacist can supply up to 30 days supply where they are in the knowledge that the patient has been supplied the medication before and is unable to obtain a supply from their doctor. Emergency supply to a patient is a discrete act and does not require a prescription to be furnished at a later date.

There is no provision in law for the loan of medications against a future prescription and pharmacists must not undertake this activity.

¹ See PSNI standards and guidance on the sale and supply of medicines July 2009

At all times pharmacists must consider the welfare of the patient first and consider that the doctor may have refused to supply a prescription for a unique medicine to the patient, the pharmacist may therefore be negating the doctors treatment plan by any supply.

Dispensing complete packs

A number of complaints have arisen where a pharmacist supplied the medication as a collection of batches and/or manufacturers or in skillets with poor labelling and no patient leaflet.

The welfare of the patient should be the primary concern of the practitioner and consent should be obtained before supply if this would cause ambiguity which may lead to patient harm.

Registration status

A pharmacist can only work in Northern Ireland if first registered with the Pharmaceutical Society of Northern Ireland. 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 such as 'not currently practising' and therefore have made a voluntary undertaking not to practise.

Where a pharmacist has been removed due to any aspect of fitness to practise ie a statutory committee removal or an article 18 removal on health grounds, the name of that person will NOT be evidenced on the register.

There is an obligation on individual pharmacists and employers to ensure that they are registered if working as a pharmacist. Not to do this puts patients at risk.

The online register is a live feed and is the most current form available. Details posted include the name of the pharmacist, registration number and date of registration. See [Search the Register](#)

Dispensing Monitored Dosage Systems MDS

There is an increasing trend for pharmacists / pharmacies to dispense 'off patient records' and not from actual prescriptions. This is a high risk issue involving patients who will often have little or no insight into their medications and implicitly trust the pharmacist to 'get it right'.

Recent cases have shown the hospitalisations of patients due to the dispensing of medicines off PMRs causing harm or distress to patients and carers.

The pharmacy SOPs should reflect that medicines dispensed should always be from current prescriptions and not tagged and repeated from records. Due diligence is also required in the labelling of dosage cassettes to ensure that the correct medicine is administered to the correct patient.

The Pharmacy Network Group PNG

The Pharmaceutical Society, DHSSPS, BSO and HSCB have recently formalised a memorandum of understanding regarding the sharing of information on complaints concerns and incidents. The organisations will proactively meet to develop quality frameworks for the recording and processing of complaints, concerns and incidents relating to pharmaceutical care. A case management system managed by the Pharmaceutical Society of Northern Ireland helps to determine the most effective method to process an individual case and allow efficient use of resources and faster outcomes for patients.

The Pharmaceutical Society and the DHSSPS currently meet bi-weekly and review and action activity in relation to complaints concerns and incidents. This will now involve the participation of the BSO and HSCB at least monthly.

Key Performance Indicators (KPIs)

In the CHRE 2007/2008 Performance Review of the health care regulators, CHRE noted that the development of key performance indicators and monitoring against them by PSNI was an area of work where specific improvements are already underway or recommended and CHRE will review progress in these areas in 2009.

The development of KPIs was therefore regarding the complaints handling processes.

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 brought to the Pharmacy Network Group (PNG) within 5 working days for allocation.

- 100% Met

Where an issue is serious, allocation must take place as soon as possible to ensure patient/public protection.

- 100% Met

Investigations (3 months)

The target is to complete the investigation of the complaint/concern within 3 calendar months. This does not include time taken by the Public Prosecution Service to consider the file. 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 on holiday it may not normally be possible to meet the 3 month time scale.

- The Pharmaceutical Society of Northern Ireland has now established with the DHSSPS that the normal time period for its completion of an investigation will be not more than 3 months in normal circumstances
- Where the regulator itself has investigations to complete these will also now be targeted to complete within a 3 month period

Public Prosecution Service (PPS) (not defined)

The time taken by the PPS is not subject to a KPI as this process is outside the control of the Department/PSNI.

After actions following consideration by PPS (10 working days)

Recommendations/after actions following consideration of file by PPS will be undertaken within 10 working days. This will include collation of file to PSNI (where appropriate).

Scrutiny Committee (2 months)

On receipt of the file, or completion of a case by PSNI, the case will be referred to the Scrutiny Committee within 2 months.

- 100% Met

Statutory Committee (6 months)

Following consideration by the Scrutiny Committee, any case being referred to the Statutory Committee, will have a hearing date of not more than 6 months from the date of the Scrutiny Committee decision.

- 100% Met

Statistics relating to cases notified to the Pharmaceutical Society

It should be noted that not all cases referenced in this report are initiated with the PSNI but are matters for information relating to any investigations being carried out by either the DHSSPS or HSCB. The regulator is advised of these matters on an information only basis. The regulator does then review the case in reference to any potential professional misconduct issues which should be addressed.

Cases opened in 2008 which were CLOSED in 2009

Issue	Cases	Average work days	Median
Criminal conviction	2	212	212
Complaint to PSNI	6	127	117
TOTAL	8	149	175

Cases opened in 2008 remaining OPEN in 2009

Issue	cases	Average work days	Median
Concern to PSNI	2	313	313
Complaint to DHSSPS	3	376	361
TOTAL	5	365	346

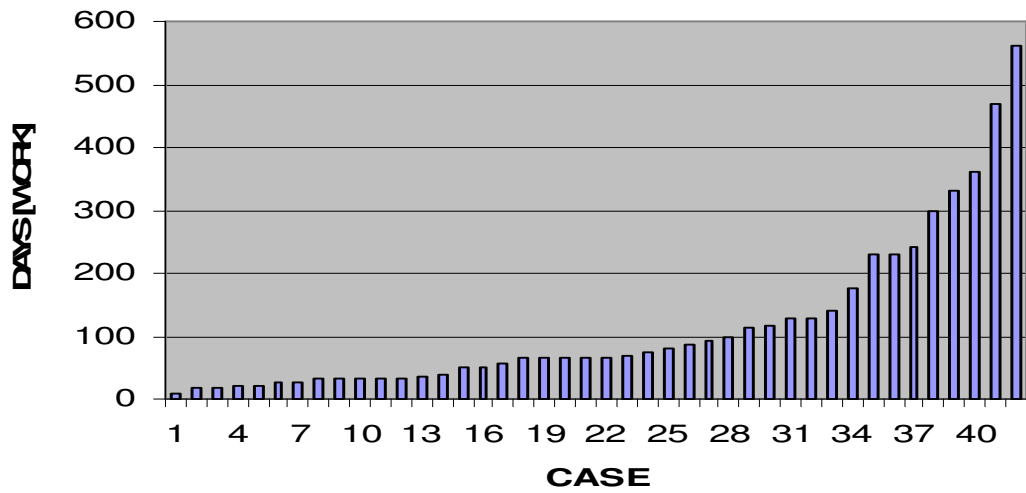
Cases opened in 2009 which were CLOSED in 2009

Issue	cases	Average days	work	Median
Self declared conviction	5	102		111
Complaint to PSNI	11	31		20
Health related issue	2	64		64
Complaint to HPSS	3	66		72
Incomplete Complaint	2	18		18
TOTAL	23	53		40

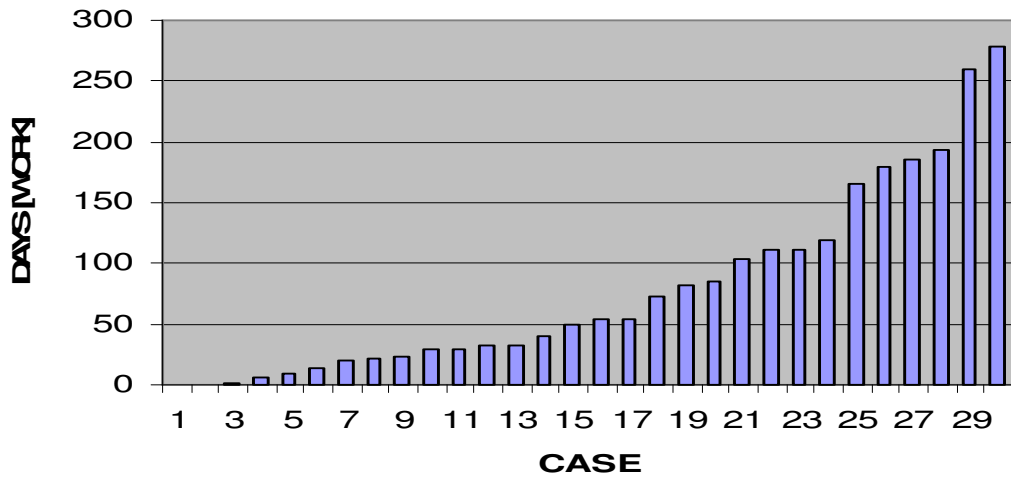
Cases opened in 2009 remaining OPEN in 2009

Issue	cases	Average days	work	Median
Complaint to PSNI	6	160		171
Concern to PSNI	4	20		16
Complaint to HPSS	24	66		64
Self declared conviction	3	71		60
TOTAL	37	77		64

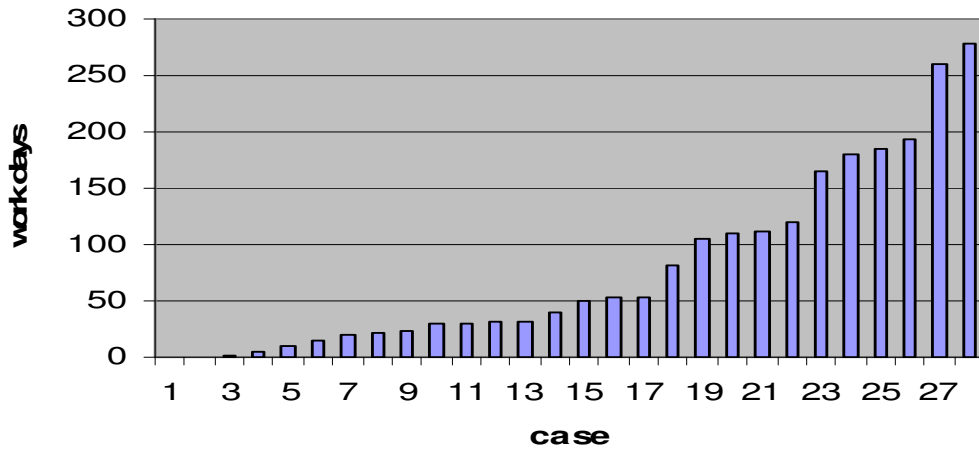
2009 CASES OPEN AT 15 DECEMBER



2009 CASES CLOSED TO 15 DECEMBER 2009



**complaints concerns convictions
originating at PSNI, cases closed in
2009**



**complaints concerns originating at
PSNI in 2009 still open**

