Regulatory Update

Pharmaceutical Society NI
Protecting Registering Regulating

NEWSLETTER ISSUE 2 May 2014

Is your CPD portfolio ready?

There are less than 3 weeks left until almost 2100 pharmacists come to the end of their first year of statutory CPD.

This means that **every registrant** wishing to retain their registration status must submit a CPD portfolio on or before **31 May 2014.**

The submission portal is now open and will close at midnight on **31 May 2014!**

So far, approximately 1500 pharmacists have created CPD cycles for the June 13/14… is your portfolio ready?

Pharmacists continue to excel at CPD

CPD has been a professional requirement of the Pharmaceutical Society NI for over 8 years.

During that time period, hundreds of portfolios have been assessed and the vast majority have met the standard.

CPD results 2012/13

Most recently, in the CPD year (2012/13), 99% of registrants who entered our processes for CPD assessment and reassessment met our standard for assessment.

Final CPD framework published

On 15 April 2014, the final version of the CPD Framework was published bringing together the previously published CPD Framework (from May 2013) and the second part of the Framework which was consulted on earlier this year.

Following the most recent phase of consultation, which closed in January 2014 the Council agreed some key changes. Amongst these are:

- **Keeping in touch days:** A registrant on maternity, paternity or adoption leave can undertake up to 10 statutory KIT days without any requirement to undertake CPD. If this limit is exceeded the registrant will be liable to undertake CPD and make a CPD submission.
- **Future application of learning:** The unrestricted use of simulation and/or 'future application of learning' in the evaluation stage of a CPD cycle should a registrant be unable to describe an actual application of their CPD learning in that CPD year.
- **Restoration to the Register after removal for CPD non-compliance:** Up to 15hours of CPD will be required from registrants within 6 months of their return to the register and will be treated as an early submission and a component of the 30hour compulsory annual submission, and not in addition to 30hours as proposed in the consultation.

CPD Framework (April 2014)

The final CPD framework (April 2004) is available on the website . Follow this link

Submit your portfolio by 31 May 2014!

The CPD standards state that you must keep a legible record of your CPD - either electronically online or as a hard copy on paper in the form and manner specified in the CPD framework

Where possible, we would encourage CPD submissions to be made online.

The system allows for easy editing of your CPD cycles —so you can start a cycle and come back to it when you have more time. **Please note** once you have submitted your completed portfolio, you will not be able to access it again and it will be formally submitted.

Please ensure that you are content with your portfolio before submitting it online.

We will continue to accept paper portfolios although we remind registrants that it is their responsibility to ensure that all paper portfolios have reached the offices of the Pharmaceutical Society NI by the submission deadline.

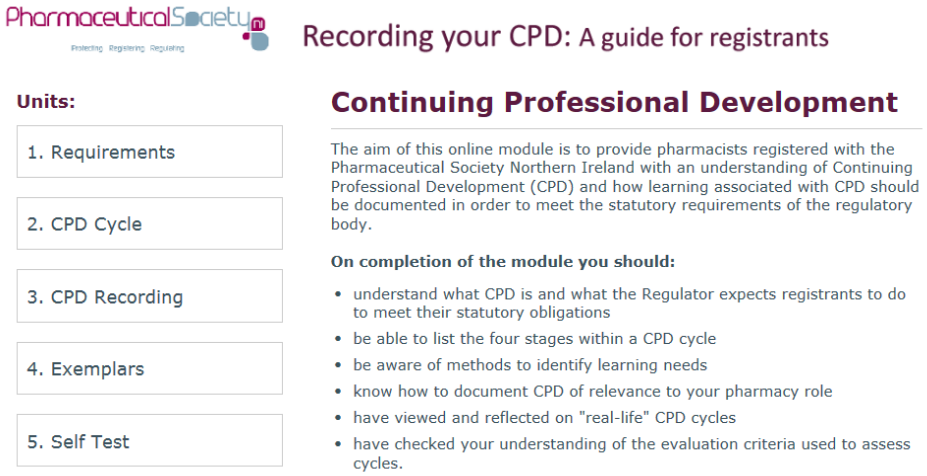
For online submissions, an automatic email will be sent as an acknowledgement that a CPD submission has been successful.

In the case of paper submission, the office will be send postal acknowledgements.

All acknowledgments must be kept as proof of CPD submission. If you do not receive an acknowledgement after making a CPD submission please contact the office immediately.

We encourage you to print off hard copies of all your CPD cycles for your personal records to keep along with evidence of participation.

How to record your CPD



We have several resources available on the CPD section of the website to help registrants record their CPD.

In particular we would direct registrants to :

The CPD Online Manual covers all aspects of the CPD process

CPD Assessment Guide which will guide you step by step through the CPD process.

The CPD Framework and Standards COMPOSITE April 2014

What happens if I don't submit my portfolio by the deadline?

If you fail to submit a CPD portfolio by the submission deadline without a 'reasonable excuse' you will have failed to comply with the requirements of the CPD Framework.

This may result in removal of registration status.

You should contact the Registrar as soon as you realise that you have failed to submit a CPD portfolio by the deadline explaining why you did not submit your CPD portfolio on time.

In cases of non-submission, the Registrar will follow the statutory processes set out by Articles 5-8 of the regulations
(The Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012)

What happens when all portfolios have been submitted?

Once all submissions have been submitted, a 10% sample will be selected – this will include a small number of registrants whose portfolios will be actively selected for assessment. For details please refer to the CPD Framework (April 2014).

Any registrant whose portfolio has been selected for assessment will be notified in early June and their CPD results will be notified to them by the end of August 2014.

Where a portfolio fails to reach the standard for assessment, a registrant will be given up to **two further opportunities in reassessment** to submit a successful portfolio.

The process of remediation is outlined in the CPD Framework and advice will be available from the Post Registration Lead, Ms Michelle McCorry, should the need arise.

Help is at hand!

In addition to the CPD online manual and Assessment Guide, there are a number of resources available to registrants to help record their CPD information

CPD Frequently Asked Questions April 2014 clarifies issues that commonly arise.

The CPD Framework and Standards COMPOSITE April 2014

All resources can be found on the CPD section of the Pharmaceutical Society NI website.

Further information

If you remain unsure about certain aspects of the CPD process and requirements please contact the Post registration lead, Michelle McCorry
michelle.mccorry@psni.org.uk

The Pharmacy Forum is also available to provide facilitation support

Pre-registration Update

Applications for Pre-registration 2014/15

Applications for pre-registration training 2014-15 are now being accepted.

Please note applications cannot be accepted after **30th May 2014**

Application forms can be downloaded from the Pharmaceutical Society NI website via the following link: http://www.psni.org.uk/pre-registration/applying-to-register-as-trainee-of-the-society/

Examination Committee

The Pharmaceutical Society NI is seeking to recruit Registration Examination Committee members.

For further information please contact:
Peter McKee, Pre-registration Lead
peter.mckee@psni.org.uk

Registration Exam 2014

The Registration Examination will be held on **Wednesday 11th June 2014**
SU Snack Bar
Queen's Students' Union
79-81 University Road, Belfast

Annual renewal of registration

The registration year for pharmacists in Northern Ireland runs from 1st June to 31st May each year.

All Annual Retention Packs have now been mailed to every registrant registered address, for the coming year.

In order to practise in Northern Ireland, all retention information, including the retention fee must be returned to the Pharmaceutical Society NI by **1 June 2014.**

Please contact the Registration Department on 028 90326927 if you have any queries.

Professional indemnity and your registration

The statutory requirement to have professional indemnity arrangements in place as a condition of registration was introduced by the Northern Ireland Assembly in November 2013.

This was necessary in order to comply with EU legislation.

The DHSSPS consultation on enabling regulations to support the introduction of this statutory requirement closed in March 2014.

The Regulations were laid at the NI Assembly on 1 May 2014 and will come into operation on 1 June 2014. Follow this link for more information.

We conducted a consultation on draft Guidance for registrants on how these regulations will be implemented in practice.

Final guidance

The consultation closed on 2 April 2014.

We will use the responses we receive, which are currently being analysed, to decide if further changes are needed.

We will then publish the finalised Guidance once it is approved by Council.

Fitness to practise procedures explained

In a recent snapshot survey of registrants, 43.3% told us that they did not understand the complaints procedures.

Feedback from recent roundtable events with pharmacists also indicated that there is a lack of understanding of the fitness to practise regime and procedures.

In response to this, in this section we provide a brief overview of the fitness to practise process and outline what happens when we receive a complaint.

We have powers to:

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

The purpose of fitness to practise procedures is not to punish pharmacists but to protect patients and the public

Fitness to Practise, complaints and concerns

Fitness to practise, including the receipt and processing of complaints, concerns and incidents are the responsibility of the Registrar.

The Pharmaceutical Society NI works in close partnership with the Department of Health, Social Services and Public Safety (DHSSPS) Pharmaceutical Inspectorate in the investigation of complaints or concerns.

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

What happens when a complaint is made?

Complaints come from a variety of different sources, including patients and the public, other healthcare professionals, primary care organisations and other regulatory and enforcement authorities.

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

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

There is also the possibility in high risk cases to refer directly to a Statutory Committee which may in certain circumstances, impose an interim order, suspend practice or impose conditions, pending a full investigation.

Decisions to close cases are all subject to review.

Additionally, cases which are deemed unduly lenient may be referred by the Professional Standards Authority (PSA) to the High Court.

Fitness to Practise Committees

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

Scrutiny Committee (Initial Proceedings)

The Scrutiny Committee meets in private and it does not hear oral evidence.

It considers initial allegations on a paper based format.

It has the power to dismiss a case, give advice issue warnings and agree undertakings if appropriate and must refer more serious cases to the Statutory Committee.

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

The Committee referred five cases on to the Statutory Committee and closed four cases.

Three cases were closed with advice and one registrant was issued a warning.

Statutory Committee (Hearings Committee)

This Committee considers cases at **public hearings** (except for health related cases).

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:

Give advice, issue formal warnings, agree undertakings, place conditions on the practise of a pharmacist, impose suspension and remove registrants from the register.

This committee also deals with interim orders, restoration applications and review hearings.

Interim order hearings

If a fitness to practise committee considers it is necessary for the protection of the public, in the public interest, or in the interests of the pharmacy professional, they may make an interim order for suspension from the register, or impose conditions on the pharmacy professional's registration.

Interim order hearings are held in private.

The Pharmaceutical Society NI does not publish information relating solely to the physical or mental health of a pharmacist.

This information is treated as confidential regardless of which Committee (Scrutiny or Statutory) hears the case.

No details of any interim order cases will be disclosed, only the determination will be made public and will appear on the online register.

Hearings and determinations

Details of statutory committee hearings are published on our website http://www.psni.org.uk/about/fitness-to-practise/

Statutory Committee outcomes

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

The determinations in each of these were as follows:

- Advice
- Suspensions for 3 months
- Conditions on practice
- Suspension 12 months
- Suspension 6 months

Interim order hearings (private) 2013

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

- One registrant received an interim suspension order made in 2012 which was reviewed and extended on two occasions in 2013, each time for six months.
- One registrant received an interim conditions order which was reviewed at the full hearing and was subsequently replaced with a suspension order of one year.
- One registrant received an interim suspension order for six months.

Fitness to Practise learnings

In each edition of our newsletter we will share the learnings from some of our fitness to practise investigations to improve understanding among registrants and to enhance safe and effective practice.

Monitored dosage systems

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

The prescription only medications supplied were not all in accordance with legislation in that medicines were supplied using historical pharmacy patient histories.

On occasion the medications supplied were either different to the strength or product authorised on the prescriptions. There were also instances of medications supplied in the absence of authorising prescriptions. No harm was suffered by patients. The pharmacist was prosecuted and convicted of a number of breaches of the Medicines Act 1968.

The pharmacist's fitness to practise was found to be impaired and their continuing registration was subject to conditions.

The pharmacist was directed to produce a personal development plan and to undertake a period of 12 months supervised practise.

Learning points

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

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

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

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

Fitness to Practise annual report

The Annual fitness to practise report will be available on the Pharmaceutical Society NI website in May 2014.

This report contains key statistics and learning points for pharmacists arising from fitness to practise cases and issues throughout 2013.

Fitness to Practise learnings

Prescriptions

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

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

The amended forms were faxed by the pharmacist to a UK manufacturer to verify a need for the medicines which were ordered by the pharmacy. The medications were supplied by the manufacturer in good faith in order to meet the immediate needs of patients.

The pharmacist however further distributed the medications through wholesale licensed supply solely for commercial gain.

Outcome

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

Learning points

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

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

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

4. The holder of a wholesale dealer licence may only legally obtain medicinal products from licensed manufacturers or licensed wholesale dealers in the UK or other EEA Member States.

   A licence holder obtaining products from outside of the regulated supply chain, including obtaining stock from a pharmacy would be in breach of their licence and could face regulatory action, and/or criminal prosecution.

Record keeping

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

Prescriptions were not always dispensed in accordance with the prescriber's directions.

There were instances of medication subject to safe custody and/or registers being dispensed in advance of prescriptions without the authority of a prescription.

The record keeping in relation to controlled drugs prescriptions and registers was poor.

No harm was suffered by patients.

Outcome

The pharmacist's fitness to practise was found to be impaired and they were suspended for six months subject to a further review.

Learning points

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

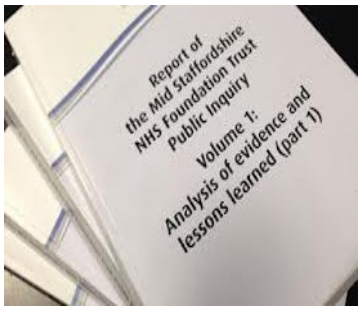
2. Adherence to pharmacy procedures [SOPs] helps to assure quality in the safe and effective supply of medicines.

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

4. Medications requiring entries in registers should be treated with extra caution and contemporaneous records should be made.

   Where prescriptions are endorsed this should again be contemporaneous and reflect the prescribers instructions.

Raising concerns



6 February 2014 marked the first anniversary of the publication of the second Francis report.

The findings from the public inquiry into the terrible events at Mid-Staffordshire NHS Foundation Trust highlighted a whole system failure and reminded us all of the consequences when concerns are not raised and dealt with effectively.

Over the past year we have been implementing actions agreed by Council in response to the recommendations in the report and subsequent reports i.e. Clwyd Heart, Keogh. To read the Council's response follow this link
Response to Francis pdf

We have made progress on a number of actions but there is still much more to do.

We are looking at our responsibilities as a professional regulator, what more we can do, how our processes can be more effective and how we work with other organisations.

All pharmacists have an ethical duty to raise concerns and act when they believe patients' safety is at risk, whatever their role is.

We will continue to keep you updated and work with you with the ultimate aim of providing a safer service for patients and public.

Priorities 2014—Response to Francis

Review of raising concerns guidance

Our 'Guidance on Raising Concerns' (2013) sets out our expectation that all pharmacists, whatever your role, whether you are an employer, employee or a locum, must take appropriate action to raise and act upon concerns

A planned review (*Action point 3)* of the Guidance is scheduled in which we will engage with registrants and other stakeholders to ensure that the Guidance is useful and explore how the guidance can be improved.

Review of complaints process

A planned review of the complaints process will also be undertaken *(Action point 8)* and promotional activity and increased engagement with registrants, patients and carers *(Action point 9)* will be considered to enhance public awareness of the process whilst ensuring that all barriers around raising complaints and issues are reduced to a minimum.

Review of Code of Ethics

In line with our response to the Francis Report, *(Action point 1)* we are in the process of carrying out a fundamental review of our Code of Ethics.

Rebalancing medicines legislation and pharmacy regulation programme board

We sit on the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board. Phase one of this work aims to improve candour by minimising the use of criminal sanctions with a specific target to improve reporting within the pharmacy profession and will also clarify many anomalies which flowed from the Responsible Pharmacist legislation in 2009. Future work will focus on supervision and hospital pharmacy.

You can find out more about the work of the programme board at: https://www.gov.uk/government/groups/pharmacy-regulation-programme-board

Should I complain or raise a concern?

If you are unsure what to do about concerns, please telephone 028 9032 6927 and one of our staff will discuss your concerns with you

Visit our website for more information on complaints and what we can and cannot investigate
http://www.psni.org.uk/about/complaints-2/

Contact us
Please get in touch with feedback on the newsletter. Is there anything you would like to see in future issues?

We would like to hear your views, so please email grainne.magee@psni.org.uk