

Welcome to update



Welcome to the fourth edition of our regulatory update in 2018.

In this edition, Dr Livingstone, President of the Pharmaceutical Society NI, outlines our plans for 2019. We introduce you to our new Policy, Standards and Communications Team and provide a reminder about the annual retention of premises on the Register of Pharmaceutical Premises.

We bring you our regular updates on CPD and Pre-registration, which should be of interest to both trainees and tutors alike.

We also provide an update on Government planning for Brexit and will continue to update you during the Brexit process.

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You can read previous editions of our Regulatory Update [here](#)

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Looking forward – Regulation in 2019 – Dr Jim Livingstone, President

It has been another busy year for the Pharmaceutical Society NI in what undoubtedly have been very challenging circumstances for pharmacy and other health and social care services in Northern Ireland. The increasing pressures on services, and particularly healthcare professionals, seem relentless – and all of this against the backdrop of an absent Northern Ireland Executive and Assembly and the potential implications of Brexit.



But as we approach the festive period, we all know it is even more important that we keep focused on the future and what we need to do to ensure safe and high-quality services for patients. I wanted to share with you our plans and priorities for 2019.

Annual Report 2017-18

You can access and read our [Annual Report 2017-18](#) to find out more about the work we have undertaken in the last year.

External Inquiries and reports

External reports such as the public inquiry into Hypotremia-Related deaths and the Gosport Memorial Hospital have reminded us of what is at stake when things go wrong for patients, when healthcare professionals make bad choices and when systems to protect and enhance quality care are flawed or even absent – patients suffer harm and the reputation of healthcare professionals can be severely damaged.

These reports, among others, raise considerable issues related to the [Duty of Candour](#), [raising concerns](#), how concerns raised are handled and how we share information and collaborate with other regulators and healthcare bodies. In 2019 we will be working on the findings, implications and recommendations made in relation to these reports and building them into our work

plans and regulatory outputs.

With this in mind, we welcome the recently published [Government response](#) to the Gosport Independent Panel report and its recommendations. Although the recommendations are focused on England and Wales, we will be carefully considering what this means for pharmacy regulation in Northern Ireland and working with stakeholders to explore any potential actions needed to bolster the regulatory framework here.

Dispensing errors defence and learning from mistakes

We have started a combined project with the Department of Health NI, the Health and Social Care Board and the Pharmacy Forum NI, directed at improving error reporting, resulting in greater learning opportunities from mistakes and near misses. This project is a result of the new defence for community pharmacists and the planned defence for hospital pharmacists and other services in relation to [dispensing errors](#). This project will continue into 2019, and we will keep pharmacists and the public informed of progress and outputs.

Improving Pharmacy Governance Arrangements

We welcomed the Government's 2018 consultation on a draft Order seeking to clarify and strengthen the governance arrangements of registered pharmacies.



Specifically, the consultation proposed changes to the [legislation governing](#) Responsible Pharmacists and Superintendent Pharmacists, with the proposal that the responsibility for relevant standards passes to the pharmacy regulators, rather than remaining within ministerial Regulations. If Parliamentary approval of the proposed draft Order is granted, 2019 will see us begin work with stakeholders in Northern Ireland, and in co-operation with the GPhC, to develop new regulatory standards in these areas.

Looking forward – Regulation in 2019 – Dr Jim Livingstone, President

Premises Standards

Council agreed new [Premises Standards](#) in 2018, which await approval to come into operation. We are presently working with the Department of Health (NI) in the development of criteria – directly linked to the new Standards – to assist pharmacy owners and Superintendents and for use by the Department of Health's Inspectorate in assessing premises. In 2019 we are planning to launch a pilot scheme in collaboration with the Department of Health, to test the criteria and corresponding inspection regime to ensure it is fit for purpose.

Once piloting is completed, we anticipate that the new Premises Standards and inspection regime will take effect during 2019 for all registered pharmacy premises. We will provide updates on the launch of the pilot scheme and its results when these are available. We will also inform all pharmacists of the implementation date of the new Standards well in advance. In preparation for this I would encourage all pharmacy owners, Superintendents and Pharmacists to study the new [Premises Standards](#).

Standards and Guidance Review

In 2019 we will continue to work on reviewing our regulatory Standards and Guidance documents, engaging with the profession and our stakeholders moving forward. The objective of this work is to ensure that we continue to have Standards and Guidance documents which are evidence-based, output focused, achievable and necessary for patient and public safety. You can find more about the review and the team carrying it out within this Newsletter.

Brexit

We are acutely aware of concerns raised and Government's planning to address potentially reduced medicine supplies in a no-deal Brexit scenario. Whilst we

are maintaining a watching brief on this important issue, our main focus has been the direct implications for the regulation of pharmacy in Northern Ireland. To this end we have engaged proactively with Government on ensuring we have the legislative powers necessary to manage any regulatory risk in a no-deal scenario, and like everyone else we are monitoring closely the potential outcomes for any negotiated agreement between the EU and the UK Government. You can find more information on Pg.6.

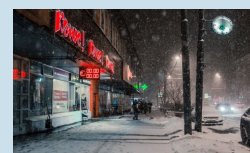
Changes to Council

On behalf of [Council](#) and the organisation I would like to acknowledge the work and dedication of Professor Martin Bradley OBE, Mr Gareth Peeples, and Ms Eleanor Magennis, who have recently stepped down from Council. Martin, Gareth and Eleanor provided Council with a wealth of experience and knowledge which will be missed, and we wish them well in their futures.

We still await the formal appointment of six new Council members by the Department of Health and we hope these can be confirmed and announced in the coming weeks.

Festive Period

Pharmacists play an essential part in caring for our community throughout the year, not least during the extremely busy



Christmas period. I would like to take this opportunity to pay tribute to the excellent work pharmacists do in many diverse settings. On behalf of the Pharmaceutical Society NI I would like to wish you all a very **Happy Christmas**, as well as a peaceful, safe and successful **New Year**.

Policy, Standards and Engagement Team

Policy Standards and Engagement Team

We have set up a new Policy, Standards and Engagement Team with a remit of providing policy support across the regulator, reviewing, renewing and promoting our regulatory standards and enhancing communications with our key stakeholders and the public.

The team, which has extensive experience in pharmacy regulation, policy development and engagement consists of:

- **Mark Neale**, Head of Public Affairs;
- **Peter Hutchinson**, Policy, Standards and Engagement Lead; and
- **Simon McClenahan**, Policy, Standards and Engagement Officer.

Standards and Guidance Renewal Project

A core function of the Pharmaceutical Society NI's work is setting Standards for pharmacy professionals in Northern Ireland to guide and support pharmacists in their scope of practice, professional development and decision making.

The Standards outlined in our [Code \(2016\)](#) are also a statement of what people expect from pharmacy professionals and reflect what pharmacy professionals expect of themselves and their colleagues.

Our Premises Standards play a similar role with regards the expectations people and pharmacists have for the services that are provided from registered premises.

In line with our [Corporate Strategy 2017-2022](#), we have initiated a review and renewal of the Code's associated [Standards and Guidance](#) documents, assessing whether our current documents remain 'fit for purpose' to aid public safety and assist pharmacists in interpreting the Code, where appropriate.

The Policy, Standards and Engagement Team will be leading on this

Consultations 

work in 2019 with the objective of renewing the current suite of documents, to ensure they are evidence-based, output focused, achievable and necessary for patient and public safety in Northern Ireland.

We want to know your views

To ensure our regulatory Standards and Guidance documents aid public safety and assist pharmacists in their work, the voice, opinion and expertise of pharmacists in Northern Ireland will be vital. In 2019, we will be seeking the views of pharmacists and stakeholders, however, if you would like to contact us about our work in general or any specific aspect of our work, you can do so by e-mail or telephone:

Contact details

Mark Neale: mark.neale@psni.org.uk

Peter Hutchinson: peter.hutchinson@psni.org.uk

Simon McClenahan: simon.mclenahan@psni.org.uk

Telephone: 02890326927



Annual retention of premises on the Register of Pharmaceutical Premises

The registration of premises to carry on the business of a retail pharmacy, maintained under Section 76 (1) of the Medicines Act 1968, expires on 31 December 2018. Payment is due on or before 1 January 2019. If payment is not made by this date, a Statutory Notice will be issued at the beginning of January which could result in removal of the premises from the Register. The cost to re-register is £317.

Last year was the first year pharmacies could complete annual retention online in Northern Ireland. Over 75% of pharmacies used the [online portal](#) in its first year. It is a convenient, fast and easy way to complete premises retention.

The Department of Health (NI) has the authority to set the fees for pharmacy premises in Northern Ireland. These remain unchanged for 2019 at:

- Initial Registration £113
- Annual Retention £155

Payments can be made by BACS, debit card or cheque.

Please note, we no longer accept credit card payments.

If you would like to pay for several pharmacies with one payment, please contact Andrea.McFall@psni.org.uk

New annual premises registration certificates will be issued to all registered pharmacies within 4 weeks of payment. Certificates can be retained on the registered pharmacy premises and may be displayed.

Newsletter Feedback

We would welcome your feedback on this Newsletter to make it as effective as possible. If you have any feedback or suggestions please contact Simon McClenahan:

simon.mclenahan@psni.org.uk

Telephone: 02890326927

CPD Update



We can report that 2635 (99.66%) of registrants complied with the CPD process for the year 2017/18. A total of 256 portfolios (11.0%) were selected for assessment of which 226 (9.7%) were randomly selected and 30 (1.3%) were specifically selected.

As we near completion of the Assessment process, the following outcomes can be reported:

Of the 256 portfolios audited:

- 228 met standard at Assessment 1
- 28 entered into Reassessment 1
- 26 met standard at Reassessment 1
- 2 entered into Reassessment 2 – final results will be available at the end of January 2019

Top Tips

Registrants should consider the following when undertaking and recording CPD activity for CPD year 2018/19:

- CPD cycles should be written clearly;
- CPD information should address the specific assessment criteria;
- All stages of each CPD cycle should relate specifically to the learning objectives identified in the reflection stage of the cycle and to the area of pharmacy practice;
- CPD cycles should, as far as possible, be recorded throughout the CPD year – giving more time to review, edit and revise portfolio prior to submission and making records of reflective practice more meaningful; and
- A personal copy of the CPD portfolio should be saved prior to submission.

Resources

CPD support materials/information are available on line, including:

[CPD Assessment Guide](#)

[CPD Online Manual](#)

[CPD Frequently Asked Questions](#)

In addition, CPD assistance and support can be sought from professional bodies such as [The Pharmacy Forum NI](#).

If you require further assistance, please contact the CPD Department by email at cpd@psni.org.uk

Pre-registration Update

Pre-registration update

As the majority of trainees are nearly half-way through their pre-registration training year, this update reviews progress and provides a number of reminders, which will be of interest to both trainees and tutors alike.

Progress with the e-portfolio:

The majority of trainees are making good progress in completing their reflective e-portfolios and are achieving the expected levels of % completion of performance standards as follows:

At 13-week appraisal: 25% completion

At 26-week appraisal: 50% completion

This is positive news and well done to those trainees and tutors who have worked to achieve this.

Ongoing monitoring of progress

Tutors and trainees are reminded that they have a joint responsibility to ensure that there is evidence of continual progress with the e-portfolio during training. We expect trainee pharmacists to be making continual progress in evidencing their competency and when progress appears behind, then it can become a matter of concern.

For this reason, in the following weeks, if progress with percentage completion of the e-portfolio remains unsatisfactory, we will be contacting those trainees concerned and their tutors to determine what barriers are contributing to this.

Appraisal update

The appraisal process is aimed at providing motivation and encouragement to trainees alongside identifying areas that require improvement. All trainees have reached their 13-week appraisal and many are approaching their 26-week appraisal. Appraisal time is also an excellent opportunity for tutors and trainees to revisit the [learning contract](#) and reaffirm the commitments made by both parties at the start of training.

What needs to happen if training arrangements change?

We recognise that life events or unforeseen circumstances can arise, which means the training arrangements made between tutors and trainees at the start of the year must change (for example tutor absence due to sickness or maternity). [The Standards for Pre-Registration Training](#) define the obligation on trainees, tutors and employers in relation to notifying us of any changes in training arrangements.

If changes to training arrangements are unavoidable, early contact should be made with the Pharmaceutical Society NI to ensure that change is managed and recognised by your regulator.

Please note - if you do not notify us of changes to training arrangements, all training subsequent to the un-notified change, will not be recognised.

Raising concerns in relation to pre-registration training

If you have any concerns about your training arrangements, you can raise those via the Pharmaceutical Society NI website or with the Pre-registration Lead directly. All concerns will be taken seriously and objectively investigated.

Protected development time for trainees

The standards for pre-registration training state that:

“A tutor must ensure that the pre-registration trainee will have onsite Personal Protected Professional Development time, agreed through discussion between trainee and his tutor. Training needs should be reviewed regularly. A minimum of four hours per working week must be dedicated to Personal Protected Professional Development Time.”

As part of the annual review of trainee experience, trainees will be asked if they have received four hours per week protected time for study and development.

Start dates for next year

For 2019-2020, pre-registration training can start between **1st July 2019 and 16th September 2019**.

The application form is now available via the following link to the [pre-registration application form](#).

Planning For Brexit

No-Deal Scenario

The Pharmaceutical Society NI has been working with the Department of Health in Belfast and the Department of Health and Social Care in London to develop statutory provisions to maintain regulatory continuity in a no-deal Brexit scenario.

To this end the Government has developed a draft Statutory Instrument – [The European Qualifications \(Pharmacists\) \(Amendment etc.\) \(EU Exit\) Regulations \(Northern Ireland\) 2018](#) - which has been laid before Parliament in Westminster.

The Regulations are being made in exercise of the power in the European Union (Withdrawal) Act 2018. The proposed Regulations would only be enacted in a no-deal scenario.

What is the current situation?

At present the [European Directive 2005/36/EC](#) on the recognition of profession qualifications sets out a reciprocal framework of the rules of the recognition of professional qualifications. This enables European Economic Area and Swiss nationals to have their professional qualifications recognised and gain access to the regulated profession in which they are qualified in another EEA State.

Aspects of the Pharmaceutical Society NI's primary Order, [the Pharmacy \(Northern Ireland\) Order 1976](#), (The 1976 Order) currently implement the relevant aspects of this EU law.

What do the proposed Regulations do?

If the UK leaves without a deal in place, aspects of the 1976 Order will not operate effectively after exit day and it will no longer be appropriate to retain other areas, given they are based on a reciprocal relationship with the EU.

In planning for this scenario, the Government wishes to retain some of the framework for the recognition of professional qualifications:

- The amended 1976 Order will provide alternative arrangements for the registration of pharmacists from EEA States who wish to register in Northern Ireland after exit day.
- The Regulations if enacted would also revoke certain other benefits and obligations within the 1976 Order, which will be inoperable, such as the [Internal Alert Mechanism](#), which UK based organisations will no longer have access to.

You can find a copy of the Statutory Instrument and a full Explanatory Memorandum [here](#).

Draft Withdrawal Agreement

A copy of the draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community can be found [here](#).