## Regulatory Update



**ISSUE FOUR—DECEMBER 2019** 

## Welcome to Update



Welcome to the fourth edition of our regulatory update in 2019.

In this edition, we bring you a holiday message from the Pharmaceutical Society NI President, Dr Jim Livingstone.

We provide the first of our regular bulletin updates on what was discussed at Council. We report on new Guidance on Patient Consent and give a reminder of the important consultation on Continuing Professional Development.

We bring an update on the work on the new Guidance on the Provision of Services. In the fifth of our series on our work teams and staff, we introduce you to Katie Quinn, the Legal Officer.

Lastly, we have included an update on preregistration and the new joint 4-country GPhC/ PSNI registration assessment which will be of interest and value to both pre-registration trainees and tutors.

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### **Review previous editions**

You can read previous editions of our Regulatory Update <u>here</u>

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### **Holiday Message**



As we approach the end of another busy year, I want to pay tribute to the excellent work pharmacists do across a diverse range of settings. As is widely recognised, they not only treat patients' physical symptoms but, the care that they give supports people's mental and emotional wellbeing. This vital work in hospitals and the community is important throughout the year, but especially during the Christmas period so many people face added pressures and illnesses.

Healthcare professionals and their regulators ultimately share many objectives. We all work to ensure that high quality care is provided to patients; that the public are protected and that public confidence in health professionals is maintained. Whilst we have clearly different responsibilities and functions, I think we would agree that achieving these objectives should be significantly enhanced by having a functioning

Executive and Northern Ireland Assembly.

As set out in our Annual Report, the Pharmaceutical Society NI has had another busy year. I am delighted we have made progress in several important areas. However, the lack of a functioning Northern Ireland Assembly and Executive has continued to hamper progress in other important areas where new legislation is needed, such as the regulation of technicians. So, a return of a working Government and Assembly is at the top of our Christmas wish list.

However, whatever happens politically, in 2020 we will continue to strive for improvement and will again seek your engagement on a range of issues, including a public consultation on new guidance on the supply of services, which has been delayed awaiting the outcome of the Government's consultation on abortion services in Northern Ireland.

Following on from the 2019 joint statements on the benefits of becoming a reflective practitioner and the high level principles for good practice to protect patients online, we will continue to work with health regulators and others on major cross sector issues. During 2020 we will work with the GPhC, and our local stakeholders on the implementation of the joint PSNI/GPhC registration assessment for 2021 and will continue to seek the implementation of the new premises' standards, the development of Regulations as to conditions to be met around character, physical and mental health and the necessary knowledge of English, the regulation of pharmacy technicians and on improving the CPD Framework.

At the Pharmaceutical Society NI, we recognise the growing pressures pharmacists are under, often in rapidly evolving new roles in community pharmacies, hospitals, GP practices, education, research and other healthcare settings. We are here to protect the public, but through our registration, standards, guidance and CPD we will continue to endeavour as best as we can, to assist and support the profession as it continues to evolve in the future.

On behalf of the Pharmaceutical Society NI, I would like to wish you and your families a very Happy Christmas, and a peaceful, safe and successful New Year.

## **Council Meeting November 2019**



Following on from the very successful Reachout Council meeting in Dungannon last year, Council held its 26 November 2019 meeting at Ulster University in Coleraine.

The first of regular bulletins to be issued following Council public session decisions is available on our website here

### **Fees**

Following a review of the projected income and expenditure for 2020/2021 Council considered the need for a fee increase.

Council decided there would be no fee increase in 2020/2021.

### **Registration Assessment**

Council considered a consultation report on the public consultation carried out between 02 August 2019 and 11 October 2019 on Proposals for a Joint GPhC/Pharmaceutical Society NI 4-Country Registration Assessment.

### Council decided to:

Adopt the joint GPhC/PSNI 4-Country Registration Assessment, introducing the revised joint assessment in 2021;

Empower the CEO to sign the Partnership Agreement between the GPhC and Pharmaceutical Society NI;

Instruct the CEO to produce an implementation and communications plan for Council's approval in January 2020.

### **Guidance on the Provision of Services**

Council considered draft Guidance on the Provision of Services and whether to proceed to publicly consult upon the document. Council considered this proposal in the context of the Northern Ireland (Executive Formation etc) Act 2019 and the Northern Ireland Office's current consultation on 'A legal framework for abortion services in Northern Ireland'.

### Council decided to:

Pause the planned public consultation to assess the outcome of the Government's public consultation and new legal framework related to abortion services in Northern Ireland. Subsequently revise the proposed Provision of Services Guidance, if necessary, and then proceed to public consultation;

Periodically review the situation; and issue a statement outlining Council's current position.

## **Council Meeting November 2019**

### **Governance review**

Council decided to approve the following actions:

A Task and Finish Groups to meet regarding the roles and responsivities of the Pharmaceutical Society NI and the Pharmacy Forum NI (the Scheme of Delegation) and the Terms of Reference of Council's new committees;

The Executive to draft a revised Scheme of Delegation for consideration/amendment by the Task and Finish Group, followed by consideration by Council;

Once approved, the CEO is to engage with the Pharmacy Forum NI to agree the Scheme of Delegation;

To continually review the situation at Council regarding risk; and

The Executive to draft terms of reference for new Committees for consideration/ amendment by the Task and Finish Group, followed by consideration by Council.

### **President**

Council considered a report from the President concerning his activities since the previous Council meeting.

Council decided that:

The CEO should engage with Pharmaceutical Society of Ireland and the GPhC with a view to securing a 3-way meeting.

### **Corporate strategy**

Council considered a report regarding progress against the Corporate Strategy.

Council decided that:

In future the Risk Register will be considered alongside the progress report against the Corporate Strategy.

### **Guidance on Patient Consent**

Council considered a review of its Guidance on Patient Consent, which included a stakeholder engagement report and proposed revised Guidance. Council noted that the revised Guidance on Patient Consent will be reviewed on the implementation of the relevant sections of the Mental Capacity Act (Northern Ireland) 2016, which relate to patients' capacity.

Council approved the revised Guidance on Patient Consent for publication.

### **Revised Guidance on Patient Consent**

The Council of the Pharmaceutical Society NI has published updated Guidance on Patient Consent following its approval at the November Council. The work forms part of the regulator's ongoing review of its Standards and Guidance documents, which support pharmacists in Northern Ireland to comply with the Professional Standards of Conduct, Ethics and Performance (2016), (the Code).

Commenting on the publication of the revised Guidance, Dr Jim Livingstone, the President of the Council of the Pharmaceutical Society NI said:

"Pharmacists have a duty to gain valid patient consent. Patient consent forms an integral part of the open and honest relationship between patients and healthcare professionals. It is vital for patient autonomy, but it also builds trust between pharmacists and their patients. Providing patients with the information they need to make informed decisions, also helps to maintain trust and professional relationships on the rare occasions when things go wrong.

"For consent to be valid, Pharmacists must ensure that patients have the necessary capacity and information to understand the treatment options and the potential consequences of receiving a particular treatment.

"We consider this updated document to have an improved structure and be more accessible to pharmacists and patients alike; providing enhanced support to pharmacists in Northern Ireland to comply with their obligations under the Code. We will be looking at this document again when the relevant sections of the Mental Capacity Act (Northern Ireland) 2016 are implemented.

"As the clinical roles of pharmacists evolve, the nature of their interactions with patients are changing making this revised guidance timely and valuable.

"I would like to thank our stakeholders for engaging with us in revising this important document and I urge all pharmacists, healthcare managers and employers in Northern Ireland to apply the Guidance".

The revised guidance can be accessed here.

## Consultation on Continuing Professional Development (CPD) Framework.

Following a review of the current CPD Framework, the Pharmaceutical Society NI is holding a 12 week public consultation on proposals to change the number of CPD cycles, the total number of CPD hours, and the overall pass mark, bringing the latter into line with post-graduate qualifications. Changes are also proposed to the requirements for those joining the register after more than 12 months out of pharmacy practice.

Subject to the outcome of this consultation, the proposed new framework will be introduced in the CPD year 2020/21. The 12-week public consultation will close at **12 noon on Tuesday 21 January 2020** and can be accessed <a href="https://example.com/here">here</a>. We encourage all interested parties to respond.

# Update on the new Guidance on the Provision of Services for pharmacists in Northern Ireland

At the November Council meeting, the Council of the Pharmaceutical Society NI considered an update on the launch of a public consultation on the Provision of Services for pharmacists in Northern Ireland.

The proposed Guidance on the Provision of Services covers issues relating to pharmacists' obligations to patients and their individual rights in circumstances of conscientious objection; patients and service users being violent, threatening violence or being abusive; and instances when a medicine or medicinal product is out of stock or unavailable.

Council considered the draft guidance in the context of the recently introduced Northern Ireland (Executive Formation etc) Act 2019 and the Northern Ireland Office's current consultation on 'A legal framework for abortion services in Northern Ireland'. Council noted that the development of its proposed guidance began before this legislative change was introduced at Westminster and the draft therefore takes no account of this legislative change. Council's proposed advice on issues of conscience relates to existing pharmacy services and the then current legal framework on the provision of services. Council considered the potential impact the planned changes to the legal framework and associated guidance for abortion services may have on its proposed guidance.

Based on these considerations, Council decided to pause the launch of the public consultation to assess the outcome of the Government's consultation and the new legal framework related to abortion services in Northern Ireland. Council will look to subsequently review and revise the proposed Provision of Services Guidance, where necessary, and then proceed to a public consultation.

The proposed Guidance on the Provision of Services will not make any changes to the existing Code of Conduct, Ethics and Performance (2016) and pharmacists should refer to this core Standards document.

### **Newsletter Feedback**

As always, 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:

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## Katie Quinn, Legal Officer



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In the fifth of our series on the Pharmaceutical Society NI's staff, we will focus on the work of the legal officer, Ms Katie Quinn.

Katie joined the Pharmaceutical Society NI in 2015 following a career as a law lecturer at Queens University. Katie worked as the senior lawyer leading the Bail project for the Northern Ireland Law Commission from 2009 to 2012. She was called to the Bar of Northern Ireland in 2013 where she practised until 2015. Katie

now works as for the organisation as an employed barrister specialising in regulatory law.

### Katie's role includes:

- investigating fitness to practise allegations;
- drafting and advising on papers for the Scrutiny and Statutory Committees;
- liaising with external legal representatives;
- reviewing and advising on NI, UK and EU legislative change which impacts upon pharmacy regulation in Northern Ireland;
- drafting Statutory Instruments for the approval of the Department of Health; and
- advising on legislative reform.

### Commenting on her role, Katie stated:

"The last year has been an interesting and busy time for the organisation as we developed new premises standards which are awaiting the enabling legislation necessary for implementation; worked with partners to ensure an smooth transition in the recognition of pharmacy qualifications post Brexit and reviewed some of our core guidance to pharmacists."

Looking to the future, Katie commented,

'Given the powers of the Council of the Pharmaceutical Society NI to make regulations, I look forward to opportunities to assist Council to enhance patient and public safety within the rapidly changing role of pharmacists and to further develop the fitness to practice processes to continue to deal fairly and efficiently with all those involved."

## Pre-registration update

As the current group of pre-registration trainees reach the first quarter of their training, the following updates will be of interest and value to trainees and tutors alike.

### **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.

### Progress with the online 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**

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.

### 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.

## Pre-registration update

### 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.

### Council approves moving towards a joint 4-country GPhC/PSNI registration assessment

Having considered the outcome of a public consultation at its meeting on 26 November 2019, the Council of the Pharmaceutical Society NI (Council) approved a joint 4-country GPhC/PSNI registration assessment. The matter was also approved by the Council of the GPhC on the 05 December 2019. The first sitting of the joint registration assessment would take place in June 2021.

Dr Jim Livingstone commented, "Council carefully considered the responses to our public consultation. We concluded that moving to create a joint registration assessment, in partnership with the GPhC, provides us with an excellent opportunity to ensure our registration assessment is sustainably secured into the future, is based on current best practice and provides the most appropriate assurance that pharmacists joining the Register in Northern Ireland are fit to practise safely.

"The draft partnership agreement we have developed with the GPhC provides us with the input, governance and accountability mechanisms we need to meet our regulatory objectives and we are grateful to the GPhC for their engagement and willing commitment to this project to date.

"The public consultation raised a number of legitimate stakeholder concerns, particularly in relation to implementing this change. We will work with the GPhC to finalise and implement a plan that will ensure students, tutors, training providers and the two universities in Northern Ireland have all the necessary information and support they need to prepare for the common final assessment in June 2021".

The common 4-country registration assessment will be set and moderated by a single Board of Assessors, which will have input from Northern Ireland appointees and will be accountable to the Councils of both regulators. It will test the application of the pharmaceutical knowledge and numeracy relevant to current pharmacy practice in both Northern Ireland and Great Britain.

There will be a common syllabus and format, described in a joint common Registration Assessment Framework. The Council of the Pharmaceutical Society NI will consider an implementation and communications plan in January 2020.