# PSNC Health Policy and Regulations Subcommittee Agenda

# for the meeting to be held on Tuesday 13th March 2018

# at PSNC Office 14 Hosier Lane, London, EC1A 9LQ

# commencing at approximately 15.30 pm

**Members:** Ian Cubbin (Chair), David Evans, Prakash Patel, Janice Perkins, Stephen Thomas.

**Apologies for absence:** None

**Minutes of previous meeting and matters arising:** The minutes of the meeting held on 10th January 2018 are set out in **Appendix HPR 01/03/18 (pages 6-9)** for approval.

**Agenda and Subcommittee Work:** The ongoing work not on the agenda is set out at **Appendix HPR 02/03/18 (pages 10-11)**.

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|---|---|
| 1 | Consider and resolve regulatory issues associated with the current CPCF and future developments; where necessary proactively seek changes to the regulatory framework, to support contractors. |

**Decision: General Data Protection Regulation (GDPR)**

PSNC has been working with other pharmacy organisations as part of the Community Pharmacy GDPR Working Party to provide guidance to the pharmacy sector. The GDPR concerns the processing of personal data of identified or identifiable living persons (data subjects) and builds on existing data protection legislation. Broadly, it makes mandatory what is currently good practice.

Attached separately, is the draft information prepared for contractors, to assist their implementation of the GDPR and the associated domestic legislation, the Data Protection Act 2017. The information is arranged in three parts, guidance, a workbook and FAQs and has been submitted to NHS Digital's Information Governance Alliance (IGA) for consideration and it is hoped, some form of endorsement.

The main outstanding issue is whether all community pharmacies will need to appoint a Data Protection Officer (DPO) (because they are deemed to be public authorities), or whether only 'large-scale' community pharmacies will need to do so; large-scale is not defined.

The subcommittee is also asked to consider/note the advice on the retention of records to which the GDPR guidance links: *Recommendations for the Retention of Pharmacy Records - prepared by the East of England NHS Senior Pharmacy Managers 2016.* This is found by searching this title on the Internet.

The information for contractors will be issued by 25 March 2018, to allow contractors 2 months to implement the GDPR. The office will provide webinars to support the publication of the information.
A separate workbook will be prepared for LPCs.

**Subcommittee Action:**

- Approve the draft guidance, workbook and FAQs

**Next Steps:**

- Publish the information by 25 March 2018

**Report: Regulation 94 appeal**

NHS England is currently seeking to recover as overpayments, claims for Quality Payments (April 2017 claim) where those claiming did not comply with the gateway criteria. ….

As part of this post payment verification work, which NHS England is undertaking on a national basis, it was noted that Regulation 94 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 referred to an appeal option but provided no appeal procedure.

DHSC agreed with PSNC arguments that there must be an appeal procedure and provided very brief draft Directions. PSNC argued that these should be more detailed, to ensure a fair procedure and sought the following to be clarified by the Directions:

(i) The appeal procedure should be as determined or approved by the Secretary of State and not the FHSAU;
(ii) There should be provision for oral hearings;
(iii) The FHSAU should be required to find facts and give reasons for any decision;
(iv) There should be provision for the FHSAU to confirm, substitute or quash any decision by NHS England;
(v) The 30-day appeal period should start from the date the contractor is notified of the decision to recover the overpayment and the appeal procedure.

…. **Appendix HPR 03/03/18 (pages 12-15)**.

One aspect of the draft Directions that is of concern is direction 4(b) which suggests that any appeal concerning the legality or reasonableness of the 2013 Regulations or the Drug Tariff is not valid. This is problematic because many disputes about overpayments are likely to relate to whether the provisions of the terms of service and/or the Drug Tariff have been followed, or not followed to the extent that there has been an overpayment. It is suggested PSNC asks for this to be removed.

Other aspects that are of concern are that with the combination of an appeal mechanism, the increasing use of post payment verification and a national approach to recovery of overpayments, there is likely to be an increase in such recoveries. Also, there is no bar to the recovery of older overpayments.

**Subcommittee Action:**

- Consider and approve, with any suggested amendments, the National Health Service Litigation Authority (Pharmaceutical Remuneration – Overpayments) (England) Directions 2018.

**Next Steps:**

- Provide a response to the DHSC.

**Report: ETP related claim**

This item concerns financial losses suffered by community pharmacy during the introduction of the Electronic Transmission of Prescriptions (ETP).

There continue to be discussions between NHS England and PSNC about the data supporting PSNC's arguments and in the last month representatives from PSNC and NHS England have visited and considered relevant evidence from NHS Digital.

**Subcommittee Action:**

- None

**Next Steps:**

- Continue to seek an agreement with NHS England and DH

## 2 Ensure administration of the regulations is undertaken properly and effectively; advising and supporting LPCs and contractors

**Decision: Community Pharmacy Contractual Framework (CPAF) (Confidential)**
…. **Appendix HPR 04/03/18 (pages 16-19)**.

….

**Next Steps:**

- Continue to work with NHS England and NHSBSA to support CPAF

**Decision: Primary Care Support England (PCSE) (Confidential)**
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**Confidential**: …. in **Appendix HPR 05/03/18 (page 20)**.

As a further matter of report, PSNC continues to be involved in monthly stakeholder meetings with NHS England and Capita on PCSE.

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**Next Steps:**

- Continue to liaise with NHS England and Capita

**Report: Rebalancing**
On 22 February 2018, the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board held a 'Partners' Forum' and presented slides:

- To update on the work done so far in relation to the Rebalancing Programme, including legislation linked to pharmacy premises standards and information, and defences for preparation and dispensing errors in registered pharmacies;
- To discuss proposals on defences for preparation and dispensing errors in hospitals and other pharmacy services, and changes to legislation regarding the role of the responsible pharmacist and superintendent pharmacist; and
- To listen to views relating to reform of the supervision of the sale and supply of medicines.

Proposals for a Pharmacy (Responsible Pharmacist and, Superintendent Pharmacist etc.) Order 2018 were, broadly:

- The Superintendent Pharmacist (SP) to be retained – SP should be a senior manager with the authority to make decisions that affect the running of the whole retail pharmacy business (not necessarily on the Board) with a general duty to secure the safe and effective running of the retail pharmacy business (always responsible). A pharmacist may act as a SP for more than one company; SP must notify GPhC when stopping being the SP; and the pharmacy regulators to set professional standard for SPs which extend beyond the sale and supply of medicines; and,
- One Responsible Pharmacist (RP) who would have statutory responsibility for the safe and effective running of a pharmacy – for the business provided at or from the pharmacy – but only

when in charge of the pharmacy. (Not responsible for establishing, maintaining and keep procedures under review and with no statutory record keeping duties.) (Not necessary for the RP to be present for the sale of GSLs.) Pharmacy regulators to set appropriate standards and have powers to set detailed statutory responsibilities
(statutory consultation for 12 weeks to commence in April 2018).

On **supervision**, it was stressed that there are currently no firm proposals for changes to legislation and, that in due course, the Board expects to share any such proposals with the Partners' Forum for discussion. The Board indicated its role is to advise Ministers and the Devolved Administrations and not make decisions. The Board's terms of reference state that it is:

"to address in parallel medicines and professional regulatory matters (e.g. supervision), which are considered to restrict full use of the skills of registered pharmacists and registered pharmacy technicians, impede the deployment of modern technologies and put disproportionate or unnecessary obstacles in the way of new models of service delivery by and/or involving pharmacy"

The full slide presentation can be found at https://www.gov.uk/government/groups/pharmacy-regulation-programme-board - Read minutes and associated papers 2017 onwards – folder title 'Partners' Forum.

There were also various additional presentations, generally from Board members, stressing the importance of patient safety as a priority, using pharmacy to the full; and making the most use of technology.

**Subcommittee Action:** None

**Next Steps:** Respond to the consultations as appropriate and continue to be engaged with the Board, as the Board permits

# PSNC Health Policy and Regulations Subcommittee Minutes

# for the meeting held on Wednesday 10th January 2018

# at CCT venues Barbican, Aldersgate House, 135-137 Aldersgate Street, EC1A 9LQ

**Members:** Ian Cubbin (Chair), Janice Perkins, Prakash Patel and Stephen Thomas.

**Together with:** Mike Pitt

**Apologies for absence:** David Evans had given his apologies.

## Minutes of the previous meeting and matters arising

The draft minutes for October 2017 were approved by the subcommittee.

There was discussion on the third AOB of the October 2017 minutes. It was agreed that the Director of Operations and Support would discuss the issue with the GPhC: concern that the views of contractors and employers should be sought at the earliest stages of development work.

## Agenda and Subcommittee Work

All ongoing matters were noted.

## Subcommittee 2018 workplan

The subcommittee agreed the majority of its workplan with minor amendments, but one proposed item was removed in its entirety: *Seek to ensure that pharmacies without an NHS contract are not involved in the provision of NHS pharmaceutical services and collection and delivery arrangements do not undermine the statutory need for registered pharmacies*.

It was suggested by some that this item was unhelpful in the context of promoting new ways of working and innovation in the profession; although all members considered that the market entry regulations should be adhered to and the office would continue to be involved in the work described in this item.

It was also suggested by some that the office could provide advice to contractors on innovative ideas for the delivery of pharmaceutical services, but the Director of Operations and Support indicated that the office already provides advice to contractors on the regulations, and delivery of service developments are covered elsewhere in the Committee's plan. In addition, there are significant resource implications with any form of innovation hub.

The agreed subcommittee 2018 workplan is attached as annex A.

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| 1 | Consider and resolve regulatory issues associated with the current CPCF and future developments; where necessary proactively seek changes to the regulatory framework, to support contractors. |

### Decision: Pregabalin and Gabapentin consultation.

The subcommittee considered the Home Office consultation on pregabalin and gabapentin and agreed with the key points outlined by the office. Additional arguments included: the need for any transitional period if the options are progressed; significant impact on other stakeholders, for example, wholesalers; impact on deliveries to patients; and no option for emergency supplies to patients.

CCA representatives indicated that members were undertaking additional analysis of the impact of option 1 in the consultation, which would be shared with PSNC. Stephen Thomas was thanked for the information he had provided to date.

The subcommittee indicated that when Tramadol became a Schedule 3 controlled drug this had caused significant problems - transferring the drug to and managing the resulting split prescriptions, as well as the storage of the drug in the controlled drugs cabinet. Such problems would be even greater with the current proposals because first, there is increased use of EPS and second, there is longer duration of treatment (more drugs are prescribed on each prescription). It was also noted that since Tramadol became a Schedule 3 controlled drug, its use had declined.

It was agreed that option 1 in the consultation is not feasible for community pharmacy to implement at a reasonable cost and option 2 is feasible only if the electronic prescription service is first fully enabled for prescriptions for controlled drugs of Schedules 2-5.

### Report: The Pharmacy (Preparation and Dispensing Errors) Order and The Pharmacy (Premises Standards, Information Obligations, etc.) Order

To manage/reduce workload, the subcommittee suggested that a PSNC briefing on the new legislation was unnecessary and an announcement of the change would be appropriate.

### Report: ETP related claim

The subcommittee noted that work on this confidential item is ongoing and its intensity had increased in recent months; there are currently weekly update meetings between PSNC and NHS England.

### Review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

The subcommittee noted the additional discussions between the Department of Health and Social Care and PSNC on dispensing doctors, distance selling pharmacies and prescription direction; also, that the Department must publish its report by 31 March 2018.

## Ensure administration of the regulations is undertaken properly and effectively; advising and supporting LPCs and contractors

### Decision: Provider Assurance/Post Payment Verification (PPV) for Advanced Services

The subcommittee noted that contractor submissions in the MUR post payment verification pilot are currently at 96% of those requested, and of those, approximately 90% have been verified so far. Also, that NHSBSA's approach to the pilot has been pragmatic and consultative, accepting contractor evidence if it is reasonable to do so.

After consideration, the subcommittee agreed proposals to extend the pilot to the New Medicine Service, on the basis that the level of requests to contractors will not increase. NHS England/NHSBSA

propose to maintain the total number of contractor evidence requests at the same level, around 550 per month, by reducing the number of MUR requests. The requests will be approximately 400 for MUR evidence and 150 for NMS evidence per month.

The subcommittee considered that asking a contractor for evidence (for MURs or NMS or both) in one month is reasonable, but not separate requests in consecutive months; usually, there should be a reasonable gap between any two requests for evidence.

The emerging PPV plan for the year was thought to be helpful and, in due course, it would help contractors to know when requests for evidence might arrive and to which periods they would relate –a sort of PPV calendar for the year.

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### Report: Approved Particulars

The subcommittee noted that all but one of the approved particulars have been updated and agreed with NHS England and will be issued in due course. The approved particulars for patient safety incident reporting will be updated after the new decriminalisation of dispensing errors legislation has been considered in detail.

The subcommittee suggested that PSNC should seek the provision of pharmacy practice leaflets electronically via the pharmacy website, rather than by hard copy.

### Report: Pharmacy Access Scheme

The subcommittee noted the various cases reported which were part of resolving outstanding issues with the scheme.

### General Data Protection Regulation (GDPR)

The subcommittee noted that guidance on the GDPR will be available soon.

The office reported that the Optical Federation is seeking an amendment to the proposed domestic legislation to be implemented alongside the GDPR, to avoid the requirement for primary care contractors to have a Data Protection Officer (DPO). The subcommittee agreed that PSNC should support the petition for this amendment to legislation.

### Primary Care Support England (PCSE)

The subcommittee noted that at the request of NHS England, PSNC has withdrawn from the market-entry project board considering the implementation and development of a market entry portal online.

The office reported that the National Audit Office is reviewing NHS England's management of its primary care support contract with Capita and has sought information from PSNC, which will be provided.

### Any other business

**CPAF:** The office informed the subcommittee that new preliminary questions are under consideration for CPAF and the subcommittee decided it should approve these before they are agreed with NHS England.

Consider and resolve regulatory issues associated with the current CPCF and future developments; where necessary proactively seek changes to the regulatory framework, to support contractors.

1. Consider and resolve regulatory issues associated with the development of a care based service.

2. Support consideration of regulatory issues associated with 2018/19 funding, for example, the Pharmacy Access Scheme and Quality Payments.

3. Consider and advise on regulatory issues associated with any move from national to local commissioning; including issues associated with provider companies.

4. Respond to any relevant Government proposals, including any on remote dispensing, distance selling pharmacies, or pharmacy supervision.

5. Contribute to, and consider the outcome of, the statutory review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, seeking to ensure that the needs based market entry system and Pharmaceutical Needs Assessments function appropriately; and that patients' choice of pharmacy is respected.

6. Consider and advise on regulatory issues involving IT and data/information and the introduction of the General Data Protection Regulation (GDPR).

7. Consider and advise on any changes to the regulatory framework, for example, the Health Service Products (Provision of Information and Disclosure) Regulations 2017 and the Falsified Medicines Directive (FMD).

8. Identify and consider issues for contractors arising out of Brexit

Ensure administration of the regulations is undertaken properly and effectively; advising and supporting LPCs and contractors

9. Resolve with NHS England and the Department of Health outstanding issues relating to the introduction of the Electronic Prescription Service (EPS) and ensure appropriate outcomes to avoid any repetition of those issues (for example, the introduction of 'discretionary' payments – see the Fun Con Plan 2018)

10. Clarify the legal issues associated with Clinical Commissioning Groups' rebate schemes for branded medicines.

11. Ensure appropriate consideration of issues relating to pharmacies in rural areas.

## Report on progress on matters previously discussed by the subcommittee (March 2018 Agenda)

| Item | Most recent action | Current status | Date of last subcommittee meeting |
|---|---|---|---|
| Judicial Review | An appeal hearing has been listed for 22 May 2018 with a time estimate of two and a half days | Open | N/A |
| General Data Protection Regulation (GDPR) | Agenda item<br><br>See NHS England for more information https://digital.nhs.uk/information-governance-alliance and the Information Commissioner's Office.<br><br>PSNC will issue advice with other pharmacy stakeholders | Open | 01/18 |
| Discretionary payments and "switching" etc. | Agenda item (confidential)<br><br>…. | Open | 01/18 |
| Information and disclosure regulations | Ongoing – a meeting with DHSC has been sought to seek to understand the obligations on community pharmacy when the regulations are introduced. | Open | |
| Post Payment Verification | PPV generally ongoing<br>Confidential: …. | Open | |
| Regs Review | The DHSC report that should be published by 31 March 2018 is awaited | Open | |
| Direction of Prescriptions | This issue has been discussed with DHSC as part of the Regs Review. | Open | 10/16 |
| Rebalancing | Agenda item<br><br>In 2016, the Director of Operations & Support has followed up requests to DH to be part of the working group on supervision, but without success. For relevant information and attendees, see: https://www.gov.uk/government/groups/pharmacy-regulation-programme-board | Open | 07/16 |

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| FMD | Delegated Acts issued. Department of Health currently holding meetings with stakeholders regarding implementation; discussion halted due to purdah convention. The lead on this issue is with SDS. For general information, see http://psnc.org.uk/contract-it/pharmacy-regulation/falsified-medicines-directive/ | Open | 07/16 |
| Safe Custody Regulations | A Home Office review of the Regulations is ongoing | Open | 01/18 |
| Rural issues | Comments of the PSNC Rural Group to be taken into account in the PSNC response to the Regulations Review. PSNC to renew efforts to seek to ensure rural GP practices are EPS 2 enabled. | Open | 10/17 |
| Out of Pocket expenses | Ongoing issues with NHS England issuing breach notices where it considers OOP expenses were claimed in circumstances not permitted by the Drug Tariff. | Open | 10/17 |
| Planned protection for patient access – PhAS | Agenda item. Most issues are now resolved – ongoing work on calculations for payments to LPS contractors. Some contractors still report issues unresolved. | 'Closed' | 03/17 |
| Approved Particulars | On 1 February 2018, updated Approved Particulars (APs) were published on NHS England's website: https://www.england.nhs.uk/publication/approved-particulars/ | Closed | |
| De-crim' legislation | A short press release will be issued in due course to announce the introduction of the Pharmacy (Preparation and Dispensing Errors) Order and The Pharmacy (Premises Standards, Information Obligations, etc.) Order | Closed | |

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