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.

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.

Health Policy and Regulation Subcommittee 2018 Plan

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.

12. Advise and support contractors and LPCs, as appropriate.