

PSNC Health Policy and Regulations Subcommittee Minutes
for the meeting held on Tuesday 13 March 2018
at PSNC Office, 14 Hosier Lane, London EC1A 9LQ

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

Together with: David Broome, Andrew Lane, Tricia Kennerley, Clare Kerr, Mark Griffiths, Jay Patel and Simon Dukes (part of the meeting), Jack Cresswell, Suraj Shah, Will Goh and Gordon Hockey.

Apologies for absence: None.

Minutes of the previous meeting and matters arising

The draft minutes for January 2018 were approved by the subcommittee.

Agenda and Subcommittee Work

All ongoing matters were noted.

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)

The Director of Operations and Support introduced the agenda item indicating that:

- a sector wide community pharmacy GDPR working party had been considering the issues;
- there are currently three information booklets providing guidance in the form of a 13-letter mnemonic DATAPROTECTED, a workbook for contractors to complete and FAQs;
- another information booklet on key information for staff may also be produced;
- the information will be issued to contractors by 25 March to give 2 months for compliance;
- various amendments are being made to the information before it is issued;
- approval for the information is being sought from NHS Digital's Information Governance Alliance (IGA), which includes a representative from the ICO;
- Views from the IGA may not be received before 25 March 2018;
- the information has been revised to include reference to PSNC templates provided to assist current IG compliance by community pharmacy;
- in effect the information for contractors is a 'GDPR patch' on the existing IG requirements.
- Separate to the GDPR work the IG Toolkit is being redesigned into a standard format for all primary care contractors and revisions will be made to the GDPR guidance to align this with the new IG Toolkit, so far as possible, so that contractors have minimal additional work to comply with the IG Toolkit for 2018/19.

There was discussion of various aspects of the GDPR and guidance including:

- the vexed question of whether every pharmacy business will need to appoint a Data Protection Officer (DPO) and the role of the DPO, and how pharmacies might share a DPO - the Director of Operations and

Support indicated that the position on DPOs remained unclear (what is known is described in the first section of the guidance) and that if every pharmacy must appoint a DPO it is hoped that there will be some flexibility in the interpretation of the DPO's role; it is understood that CCGs will provide DPOs for GP practices;

- the overall structure of the GDPR helpfully pushes back against consent, unless it is genuine and can be withdrawn at any time, and permits the use of personal data within various business relationships when it is necessary for that business relationship;
- Consent as part of pharmacy practice remains important;
- the retention periods stated in the NHS guidance on retention of records documents may need to be reviewed;
- the information should be issued as a version (e.g. 1) so that it can be updated and amended as further guidance is issued;
- the information should be issued as Word as well as pdf documents, to ensure contractors can complete the workbook in its electronic form;
- the close to final version provided to the community pharmacy GDPR working party later this week should be circulated to committee members.

It was agreed that PSNC, as part of the community pharmacy GDPR Working group, should issue the information documents as planned after final revisions.

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

Decision: Community Pharmacy Contractual Framework (CPAF)

The annual CPAF process has been in place for three years and in this fourth year, NHS England has decided to replace four of the ten screening questions and amend one as follows:

- Q1 – Standard operating procedures (SOPs);
- Q2 – Prescribed Medicines Advice;
- Q3 – Storage of Prescribed Drugs and Return of Unwanted Medicines;
- Q5 - Owings
- Q4 - Dispensing repeat prescriptions (amended question)

Although PSNC had liaised with NHS England on its proposed replacement questions, there was concern that the balance of the 10 screening questions had not been considered to ensure they were challenging, but also reflective of contractor compliance with the terms of service. There was particular concern with the question on summary care records.

It was agreed that a discussion should be arranged with NHS England and NHSBSA for the issues to be discussed, with a view to revision of the questions this year or next.

Primary Care Support England (PCSE)

The subcommittee noted that PSNC had met with the National Audit Office, which was investigating NHS England's management of the Primary Care Support contract with Capita.

It was also agreed that PSNC should consider, as a significant stakeholder, any proposals by PCSE/Capita for a web portal for market entry applications, ensuring so far as possible, that implementation of any new system is properly resourced and managed by PCSE/Capita to avoid problems for contractors and LPCs.

Report: Rebalancing

The committee noted the report in the agenda on the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board's Partners Forum meeting on 22 February 2018, in particular that:

- (i) 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).
- (ii) on **supervision**, currently, the Board has no firm proposals for changes to legislation and in due course expects to share any such proposals with the Partners' Forum for discussion.

Any other business

RPS guidance on the Safe and Secure Handling of Medicines in all Care settings:

There was concern that the proposed guidance had received insufficient community pharmacy input to date and the guidance should be reconsidered and revised. It was agreed that PSNC would provide a short response to the consultation.