PSNC Legislation and Regulatory Affairs (LRA) Subcommittee Agenda

For the meeting to be held on Wednesday 22nd May 2019

At 14 Hosier Lane, London EC1A 9LQ

Members: Ian Cubbin (Chair), Marc Donovan, Jas Heer, Janice Perkins, Stephen Thomas.

1. Welcome from Chair
2. Apologies for absence
3. Conflicts or declaration of interest
4. Minutes of the last meeting in February and April 2019 **(Appendix 01/05/2019 and 02/05/2019).**
5. Matters Arising

Action

6. Consolidations (confidential) **(Appendix 03/05/2019)**
7. The rebalancing board's proposed legislation on the responsible pharmacist (confidential) **(Appendix 04/05/2019)**
8. Rural community pharmacies (confidential) **(Appendix 05/05/2019)**
9. Prescription direction (confidential) **(Appendix 06/05/2019)**

Report

10. Brexit update – the notes of two recent meetings of the Community Pharmacy Brexit Forum are attached (confidential) **(Appendix 07/05/2019)**
11. Community Pharmacy Assurance Framework (CPAF) **(Appendix 08/05/2019)**
12. PCSE market entry web portal **(Appendix 09/05/2019)**
13. Pharmacy Manual **(Appendix 10/05/2019)**
14. Any other business

Pharmaceutical Services Negotiating Committee

Legislation and Regulatory Affairs Subcommittee

Minutes of the Legislation and Regulatory Affairs Subcommittee meeting held on 6 February 2019.

Members: Ian Cubbin, Stephen Thomas, Janice Perkins, Jas Heer, Marc Donovan.

In attendance: Mark Burdon, Peter Cattee, Gordon Hockey, Andrew Lane, Bharat Patel, Adrian Price, Sam Fisher, Fin McCaul, Sian Retallick and Has Modi.

Apologies: There were no apologies for absence.

Conflicts of Interest/minutes: There were no additional conflicts of interest declared. The minutes of the meeting in October 2018 were accepted as a true record of the meeting and there were no matters arising.

Item 1 – LRA priorities for 2019 - open

1.1 The subcommittee noted and agreed the subcommittee's priorities for 2019.

Item 2 – Community Pharmacy Provider Companies – no longer confidential

2.1 The subcommittee noted the agenda paper and Gordon Hockey outlined the main legal changes as follows:

- Affiliate membership available to all contractors in the region (to apply the rules to those providing services – affiliate membership can be taken up at the time a contractor signs up to provide a service).
- The appointment of observers to the board (e.g. to enable CCA and AIM company reps to observe the work of the provider company) (the observers must not act as directors, but the provider company should have unity of purpose with CCA and AIM observers present and making relevant observations).
- A provision to enable the board and PSNC to agree a PSNC observer to the board.
- The purpose of the provider company set out in the rules to make clear its work is for all contractors in the designated areas; and to confirm that services designed by the LPC may be delivered by the provider company.

2.2 There was discussion about contractor compliance with service requirements and how standards of service are ensured. It was agreed this should be explored further.

2.3 It was noted that there are various issues to be resolved including how to remove directors who are not re-elected annually, clarifying whether non-LPC directors must be contractors

and ensuring that the purposes of the provider company are wide enough to encompass all trading activity that might support contractors in the area.

2.4 There was agreement that the company articles and rules, with necessary revisions, were appropriate to be made available to LPCs for provider companies, albeit that revisions would be undertaken as the structure was used and any issues identified.

Action 1: Complete the company articles and rules; make them available to LPCs and progress with GMLPC.

…

Item 4 – Brexit, Serious Shortage Protocols draft legislation – no longer confidential

4.1 The agenda paper was noted, and the subcommittee noted with approval the changes made to the statutory instrument on Serious Shortage Protocols (SSPs).

The committee noted the ongoing work:

- Community Pharmacy Brexit Forum discussions.

- Command and control structures for the provision of information to contractors are being developed within DHSC and NHS England.

- The importance on ensuring the messaging on current shortages - supply issues and concession pricing where generally there is availability of the medicine - are kept largely separate from discussion of no-deal Brexit contingency planning for a future possible event; so that the message to the public and patients that planning is being undertaken and patients do not need to stockpile medicines and that prescribers do not need to write longer prescriptions is maintained – as contractors have been asked to do within the DHSC Operational Readiness Guidance. Accepting that Brexit may be a factor in current shortages.

4.2 Gordon Hockey indicated that draft regulations on SSPs for inclusion in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (Regs) had been received but had not been circulated because DHSC is revising them further. The key points, which related to issues that would be considered by the committee tomorrow, were as follows:

- The statutory instrument on SSPs related to POMs only but DHSC considered that SSPs should apply to POMs, Ps, GSLs and appliances. However, DHSC should have consulted on the additional categories with interested parties. Gordon Hockey indicated that he had suggested to DHSC that PSNC would accept the broadening of SSPs in the Regs, in the public interest. The subcommittee agreed with this approach.

- SSPs should not be mandatory and the Regs should state that if an SSP applies a contractor 'may' provide a different product or quantity but is not obliged to do so. The contractor

may have enough stock to fulfil the prescription or may decide that it is not reasonable or appropriate to use the SSP. The subcommittee agreed with this approach.

- The Regs should provide that the dispensing pharmacist must label the dispensed medicine with the number of the SSP – the number for that SSP allocated by DHSC. The subcommittee agreed this was manageable provided that the number was not too long.

- The Regs should provide that the dispensing pharmacist must endorse the prescription in a manner described in the Drug Tariff. There was discussion on the practicality of this with electronic prescriptions. It was reported that DHSC had indicated that PMR/EPS capability for NCSO endorsements would be used for this. At a recent meeting with DHSC, PSNC had indicated that it could not give assurances that this endorsement route would be practicable for community pharmacy and it was being explored. DHSC had indicated that if it is not practicable, other options would be explored. The NCSO capability has not been used since 2013. In addition, there were issues with inaccurate remuneration under the NCSO route which could surface again. The subcommittee was informed that steps are being taken to clarify whether the NCSO route for endorsements is practicable. In any event, the subcommittee preferred endorsement of the hardcopy dispensing token which would be submitted to NHSBSA for payment. It was suggested that a copy of the endorsed token could be sent to the GP prescriber for his or her records as required (see a later point) and this approach would also lead to better pharmacy records of SSP dispensing.

- Noting that SSPs may seek to change the quantity, strength or formulation, or provide generic (including brand for brand or brand for generic) or therapeutic substitution – the Regs should provide that the dispensing pharmacist must notify the GP of any therapeutic substitution or any other change where this is professionally appropriate; with guidance to be provided on when it is professionally appropriate. The subcommittee agreed with this approach.

- Where a pharmacist considers that it is unreasonable or inappropriate to supply against an SSP (and cannot supply a prescription with reasonable promptness), but may be able to supply against the prescription within a 'reasonable timescale' – a period of time longer than reasonable promptness, but with some urgency – the requirement to act with reasonable promptness does not apply. Noting that the term 'reasonable timescale' is undefined and flexible, the subcommittee agreed with this provision.

- Where the pharmacist considers that it is unreasonable or inappropriate to supply against the SSP and cannot supply against the prescription, it is likely that the dispensing pharmacist will have to advise the patient to return to the prescribing GP. There was discussion about this proposed requirement, and it was suggested that the patient might seek to have the prescription fulfilled by another community pharmacy rather than go back to the GP. It was reported that this provision was opposed in discussions with DHSC

as unnecessary given the pharmacist's responsibilities to a patient, but the Department seemed adamant that it should be included to ensure patients were not left with no supply and no advice.

- There was discussion of the workload involved and it was agreed that broadly, this comprised – understanding the SSP protocol and checking it is current and has not been withdrawn; liaising with the patient and managing this important clinical and business relationship; additional work ensuring an appropriate pharmacy record; managing the change to the dispensing label and potentially producing additional labels; labelling with the SSP number; making an appropriate endorsement on EPS or the dispensing token; reporting to the GP, if and as appropriate; and any additional work when the original product is supplied again.

- There was discussion on any proposed fee for dispensing against an SSP, but it was reported that the DHSC position was that there was no additional money available and that any consideration of additional workload could be considered in the next round of negotiations (similar to the position with FMD). It is notable that the majority of supply chain no-deal planning is being borne by the Industry but will be recouped in the price of medicines to community pharmacy. Publicly, DHSC has justified no additional fee for SSPs on the basis that community pharmacy would save time by not having to contact the GP. The subcommittee indicated that a fee ought to be available for supply against an SSP and that the DHSC impact assessment was incorrect.

- VAT may be chargeable on SSPs and DHSC indicated that it would ensure that contractors did not lose out and is seeking to do so by ensuring that necessary amendments to the Charging Regulations indicate that the supply is against a prescription for the purposes of those Regulations and thus should be for VAT purposes. DHSC has indicated that it will address this issue.

- If the prescription charge applies, it will apply to the supply made against the SSP, even if the quantity supplied is reduced. It was recognised by DHSC that this would be unpopular. The subcommittee indicated that PSNC's position ought to be that no prescription charge is payable for supplies against SSPs.

4.3 It was noted that the committee would discuss the main issues the following day.

Action 2: Subject to decisions at committee, progress work on the regulations associated with SSP and Brexit generally.

…

…

Item 7 - Technology – no longer confidential

7.1 The report was noted and in particular that PSNC will establish a Technology Forum.

Action 3: Establish a Technology Forum

Item 8 - Data Security and Protection Toolkit – open

8.1 The report was noted.

…

…

Any other business

There was no other business.

Date of next meeting

The date of the next subcommittee meeting is 22 May 2019.

List of Actions:	Relevant person(s) initials
Action 1: Complete the company articles and rules; make them available to LPCs and progress with GMLPC.	GH
Action 2: Subject to decisions at committee progress work on the regulations associated with SSP and Brexit generally.	GH
Action 3: Establish a Technology Forum	GH

Pharmaceutical Services Negotiating Committee

Legislation and Regulatory Affairs Subcommittee

Minutes of the Legislation and Regulatory Affairs Subcommittee meeting held on 25 April 2019.

Members: Ian Cubbin, Stephen Thomas, Janice Perkins, Jas Heer, Marc Donovan.

Apologies: Marc Donovan gave his apologies.

Conflicts of Interest/minutes: There were no additional conflicts of interest declared.

Item 1 –Serious Shortage Protocols – no longer confidential

1.2 The subcommittee noted the paper prepared by the office, which set out the main provisions of the National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (draft regs), which was annexed to the paper.

1.3 The main provisions of the draft regs which were agreed were as follows:

a. The scope of the regulations extends SSPs beyond that of the HMR 2012 and POMs, to other medicines and medical devices (Reg 2 of the attached). All pharmacy stakeholders agreed to this approach.

b. A contractor claiming payment for an SSP against an EPS prescription may do so by claiming using a hard copy dispensing token (and marking the EPS prescription as not dispensed) or claiming through the NCSO mechanism on the EPS system) (Reg 3 of the attached)

Note: The ability to claim using hard copy dispensing tokens was one of the two areas (with sufficient funding via fees) that PSNC identified as essential in order for contractors to be able to dispense medicines against SSPs). Alastair and Dan have done a lot of work on this and will provide guidance to contractors as part of the overall PSNC briefing on SSPs.

Claims against paper prescriptions are only the prescription
(All claims will have to be made in accordance with the Drug Tariff requirements – in effect to identify the changed quantity or new drug.)

c. A contractor must consider whether it is reasonable and appropriate to dispense against an SSP instead of a relevant prescription (for any SSP that is issued) (Reg 4(2) 5A1 and 2) of the attached).

d. A contractor must supply against an SSP with reasonable promptness and in accordance with the SSP and only if the supervising pharmacist - using his or her professional skill and judgement - considers that supplying a different product or quantity against the SSP is reasonable and appropriate (Reg 4 (5A3) of the attached).

e. The contractor must endorse the prescription appropriately (Reg 4(2) 5A4a) of the attached).

f. If the SSP is of therapeutic substitution (a different product with similar therapeutic effect) OR if agreed with PSNC, the contractor must notify the GP (Reg 4(2) 5A4b) of the attached) when supplying against that SSP.

   Note: DHSC has indicated that this is likely to be by NHS mail (if so, we need relevant GP e-mail addresses) and probably do so with 24 hours.

g. If the supervising pharmacist considers that it is not reasonable or appropriate to supply against the SSP and is able to supply the originally prescribed medicine within (and this is a new term) a 'reasonable timescale', the requirement to supply the medicine with reasonable promptness does not apply (Reg 4(2) 5A5 of the attached).

   Note: having reasonable timescale undefined is helpful. It suggests some urgency to supply, but not as much as reasonable promptness.

h. Certain general provisions for 'preliminary matters before providing ordered drugs or appliances' and 'providing ordered drugs or prescriptions' in the terms of service (para 7 and 8 of schedule 4 of the Regs) continue to apply (Reg 4(4) a-d) of the attached) as follows:
   i. Ask for satisfactory evidence of any exemption and advise as appropriate
   ii. Endorse a non-EPS prescription if no satisfactory evidence provided
   iii. Include such relevant info as required by the regs if an EPS prescription submitted
   iv. Necessary arrangements for measuring and fitting appliances under SSPs
   v. Must comply with relevant standards
   vi. Provide readily available (original pack) dispensing
   vii. Dispense in a suitable container

i. The dispensing label for an SSP supply must include information that it was supplied in accordance with an SSP generally and the particular SSP concerned, for example, 'Supplied under SSP [*identifying number*]' (Reg 4(4)e) of the attached).

j. Once supply has taken place against an SSP in relation to a prescription, that prescription is spent (cannot be used again) (Reg 4(5))2B) of the attached).

k. If the contractor refuses to supply against an SSP because the supervising pharmacist considers supply to be unreasonable or inappropriate; and if the contractor is unable

to supply against the (original) prescription within a reasonable timescale; the contractor must provide appropriate advice as necessary (*it won't be necessary if the patient can be directed to a nearby pharmacy that may have relevant stock*) about returning to the prescriber for a review of the treatment (Reg 4(5) 2C) of the attached).

l. Where the contractor cannot supply against the SSP for an appliance (or carry out a stoma appliance customisation), and the patient consents, the prescription may be referred to another contractor/pharmacy. If the patient does not consent, the contractor must provide the contact details of at least 2 contractors able to provide the appliance etc, if the contractor knows these details (Reg 4(6) of the attached).

m. Amendments to the Charging Regulations follow later in the draft regs. These link supply against the SSP to the prescription and the dispensing token as appropriate. These were first drafted to include a prescription charge in all cases but have been revised recently on the basis that there will be no charge if 'if a smaller quantity of drugs or fewer appliances will be supplied under the SSP. This is what PSNC suggested. This position does not have formal approval.

1.4 The subcommittee noted the terms 'supervising pharmacist' and 'reasonable timescale' were undefined, but sufficiently clear in the context of the draft regs.

1.5 It was reported that there was additional work ongoing in relation to endorsements to provide information to contractors on the various ways they could claim for reimbursement/remuneration and the practical issues associated with each way.

1.6 It was agreed that contractors would need an appropriate PSNC Briefing and FAQs to answer additional questions they may have about implementing SSPs.

1.7 The discussion at NT of an appropriate fee level was reported briefly and the subcommittee indicated that agreement of the draft regs should be linked to agreement of fees, as these additional regs will add to the requirements of the essential service dispensing medicines.

Recommendation: PSNC agrees the draft National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019, subject to appropriate remuneration.

Any other business and date of next meeting

There was no other business and the date of the next subcommittee meeting is 22 May 2019.

List of Actions:	Relevant person(s)
Action 1: Inform DHSC that draft regulations agreed in principle	GH
Action 2: Committee to consider LRA recommendation to approve the draft regulations and consider fees.	GH

…

Annex A

…

…

Annex A

...

…

…

Annex A

…

Annex B

…

Annex C

…

…

Subject	Community Pharmacy Assurance Framework (CPAF) 2019/20
Date of meeting	22/3 May 2019
Subcommittee	LRA
Status	Open following the public announcements of CPAF
Overview	The paper provides an update on NHS England's contract monitoring arrangements for 2019/20.
Proposed action(s)	None
Author(s) of the paper	William Goh

1. The office has liaised with NHS England in relation to CPAF arrangements for 2019/20 and it is anticipated that the CPAF screening survey will run for 4 weeks from early June (to be confirmed) and timings for other aspects of the contract monitoring process are expected to follow timings similar to previous years.

2. The subcommittee will be aware that last year, the contractor response rate was 98.2% which was excellent taking into account that the CPAF screening questionnaire which consists of 10 active questions was amended with the retirement of two questions and the addition of two new questions in relation to safeguarding and the pharmacy-based audit.

3. NHS England has provided two main points of feedback arising from last year's CPAF screening survey results with regards the two most recent questions. Firstly, in relation to safeguarding, there was some misunderstanding as to what is required to achieve aspirational level 3 and secondly, in relation to pharmacy-based audits, greater awareness of the alternative practice audits which could be conducted could help.

4. The office will update the website and update guidance to assist contractors including clarification on the points feedback by NHS England.

5. Contractors who do not complete the CPAF screening questionnaire are more likely to be invited to complete the full CPAF questionnaire in October/November 2019 and possibly receive a contract monitoring visit in the first quarter of 2020.

Subject	Primary Care Support England market entry web portal
Date of meeting	22 May 2019
Subcommittee	LRA
Status	Open (but not the name of the individual)
Overview	An update of the ongoing work with PCSE in relation to market-entry and related matters.
Proposed action(s)	None
Author(s) of the paper	William Goh

PCSE stakeholder meetings

1. The office continues to be involved in bimonthly stakeholder meetings with NHS England and PCSE/Capita. Reports received by the office concerning market entry issues have reduced in recent months but where contractors/applicants do raise issues, the common theme tends to centre on delays and timeliness issues to the determination of applications. Many of the applications which need to be escalated concern delays in the applicant's fitness to practise information.

2. On 8th May 2019, representatives from PCSE attended the office to provide a general operational update and demonstrate a test version of the online portal. The office continued to emphasise and reiterate the importance of resolving delays to fitness to practise confirmation.

Online Market Entry portal

3. On the 8th May, PCSE demonstrated a test version of the online portal showing screen shots of the new system, of the functionality for contractors, PCSE internally and NHS England. The online portal will eventually replace the 30+ paper application forms currently available but when launched (expected late 2019) across England will, at least initially, run parallel to the paper form applications. The portal will also include all "market exit", consolidation applications etc. There is also scope within the specification for pharmacy contractors to apply to change their core hours and give notice to amend their supplementary) hours but PCSE are in discussions with NHS England as to whether this is work that they will carry out on their behalf.

4. The office provided observations and comments and made clear that it must be fit for purpose and tested by contractors and others who are going to use it. Comments and observations included: greater visibility of the expected and actual timeline of an application. PCSE have agreed to arrange a session hosted at PSNC offices in London to demonstrate PCSE online to contractors and will offer some contractors involvement with user acceptance testing/early adopter of PCSE online.

5. PCSE also provided reassurance that …, Senior Advisor at Primary Care Commissioning has been involved in the development of the portal to ensure that the 2013 regulations are followed. To coincide with when the portal goes live, PCSE intend to develop and to publish FAQs and a user guide.

6. The office also discussed the issue of LPC access to portal information (on market entry applications for their area) and PCSE have agreed in principle to provide LPCs access to collated information, based on notifications to LPCs; to include also information of commencement notices and closure notices. This is likely to be a monthly report of market-entry activity handled by PCSE.

7. The office also reiterated a long-standing request for a direct telephone line to the market entry team to expedite relevant queries for applicants (i.e. not via customer services which usually simply refers the call to the market entry team), particularly for minor queries on applications. PCSE appeared to be receptive to this request.

Subject	Pharmacy Manual
Date of meeting	22 May 2019
Committee/Subcommittee	LRA
Status	Open
Overview	To note NHS England's publication of a revised Pharmacy Manual
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Background

1. NHS England has been developing a revised Pharmacy Manual over the course of 2018 and shared an early draft with PSNC.

The revised Pharmacy Manual

2. The executive summary in the Manual provides an overview of the changes as follows:

Part 1 - Contains information that is relevant to both NHS England and Primary Care Support England.

1 Introduction and glossary
2 NHS England's decision-making structure
3 Delegated decision-making
4 Fitness and applicants

Part 2 - Contains procedures for the processing of routine and excepted applications, work that is undertaken on behalf of NHS England by Primary Care Support England.

Minor amendments have been made to reflect the roles of Primary Care Support England as the processor of applications and NHS England as the body that makes all decisions relating to applications. In addition, steps have been added to the market entry procedures to set out the process to be followed where a successful applicant requests a timescale within

which to submit a notice of commencement or consolidation. Annexes to this Part contain the template application forms, letters, reports and notices to be used in the processing of applications.

Part 3 - Contains procedures, guidance and template letters and documents for NHS England staff in the commissioning of pharmaceutical services.

The information specific to the function of NHS England commissioning teams has been drawn out into this section into the chapters described below:

28. New chapter which focuses on the decisions that NHS England will need to make as an application is processed.
29. New chapter which contains guidance for pharmaceutical services regulations committees on the determination of specific types of applications.
30. New chapter providing guidance to NHS England staff on the powers that may be exercised where concerns are raised regarding a contractor's fitness to practise.
31. Procedure for the determination of controlled localities.
32. New chapter which sets out the responsibilities on NHS England regarding the determination of applications from GPs who wish to either start dispensing or dispense to a new area. It also covers the determination of serious difficulty applications.
33. Advanced services.
34. New chapter providing guidance to NHS England staff on the commissioning of enhanced services.
35. Opening hours.
36. This chapter has been updated to reflect the role of NHS Prescription Services in provider assurance.
37. New chapter setting out the procedures to be followed where a contractor closes premises.
38. New chapter providing guidance to NHS England staff on matters relating to pharmaceutical services finance.