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.

2.3It 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.

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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 additional 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.

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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.

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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