

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee Agenda

For the meeting to be held on Monday 7 September 2020

By Zoom from 6 - 7pm

Members: Ian Cubbin (Chair), Marc Donovan, Sunil Kochhar, Janice Perkins, Stephen Thomas.

1. Welcome from Chair
2. Apologies for absence
3. Conflicts or declaration of interest
4. Minutes of the meetings in May 2020 (**Appendix 01/09/2020**)
5. Matters Arising

Action

6. NHS amendment Regulations (**Appendix 02/09/2020**)
7. Consultation on proposed changes to the Human Medicines Regulations relating to COVID-19 and flu (**Appendix 03/09/2020**)
8. Supply of dispensed medicines from pharmacy premises that do not have an NHS contact (**Appendix 04/09/2020**)

Report

9. Any other business

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee

Minutes For the virtual meeting held on

Wednesday 29 July 2020

Members of LRA present: Ian Cubbin (Chair), Marc Donovan, Janice Perkins, Stephen Thomas.

In attendance: David Broome, Sam Fisher, Gordon Hockey, Tricia Kennerley, Sunil Kochhar, Layla Rahman.

Welcome from the Chair

1. The Chair welcomed everybody to the meeting.

Apologies for absence

2. There were no apologies for absence.

Conflicts or Declarations of Interest

3. Conflicts of interest: There were no additional conflicts of interest declared.

Minutes of the last meeting

4. The minutes of the subcommittee meeting held on 18 May 2020 were approved.

Actions and Matters Arising

5. Gordon Hockey indicated that the set of principles or arguments for the continued provision of flexible services had not been drafted.

[This has since been drafted and representations made to DHSC and NHSE&I as follows:

On 1 September, the activated emergency regs provision end and this is a request for these provisions to be extended. It is on these 'activated' regs that most of the NHSE&I SOP hinges for opening hours and I have discussed this with XXX.

We need the emergency declaration from the Secretary of State to continue beyond 1 September 2020 – and a number of arguments and observation why are set out below:

- *Contractors need to be able to respond quickly to the changing circumstances of COVID-19, particularly in surge areas, for the benefit of patients to ensure continuity of supply of medicines and other pharmaceutical services;*
- *Staff illness and absence may still be an issue in some areas of the country and contractors need to be able to flex their opening hours accordingly at short notice;*
- *Contractors can make necessary changes following 24 hour notice to NHSEI, but without NHSE&I agreement, which means the ability to respond does not rely on NHSE&I capacity to provide approval in advance;*
- *NHSE&I still retains overall control and may refuse applications for flexible provision of pharmaceutical services and may do so retrospectively if a decision cannot be made during the 24 hour notice period;*
- *This flexibility is not a ‘open ticket’ for contractors because flexibility is agreed by NHSE&I only if there is good reason for it;*
- *This flexibility provides the option for closed door working if required, but subject to NHSE&I approval; and,*
- *The existing system in the regulations for approval of hours is too slow to ensure manage these needs during the ongoing pandemic.]*

The Pharmacy Access Scheme

...

Hub and Spoke

11. The paper on hub and spoke dispensing was noted and in particular that there will be a formal public consultation on hub and spoke dispensing between legal entities (which could be before the Act comes in or after) so PSNC has not missed the opportunity to comment formally on the proposals during the COVID outbreak (even though the Medicines and Medical devices bill is now continuing to progress in Parliament).

12. Gordon Hockey indicated that the purpose for this paper was to re-engage on the issues, since the subcommittee had not considered the issues since February 2020, noting the CCA and NPA roundtable discussions on this earlier this year. Also, that it may also be helpful to take a step back and consider the issues PSNC wants the DHSC to consider in its public consultation. For example, what are the issues that PSNC wants the DHSC to consider to ensure dispensing is fair for the sector as a whole?

13. Issues identified for hub and spoke dispensing between legal entities included:

- a) How is it introduced by a contractor – what trials or checks are necessary to ensure patient safety of the process – and what arrangements should be in place to ensure quality control and what are the arrangements for recalls;

- b) What contingency issues will be established to ensure continuity of supply for patients in the event of a large automated unit being unable to function;
 - c) Any changes to legislation should not ‘mess it up’ for existing contractors carrying out hub and spoke dispensing within one legal entity – this is part of fairness for all – fairness for both Independents and Multiples (point 6 in the asks attached as an annex answered);
 - d) A glossary of terms would be helpful and recognition that automation is not the same as hub and spoke dispensing – some contractors may choose hub and spoke dispensing that is not automated;
 - e) Who is responsible for what in the process, between the two legal entities;
 - f) Clarity on which regulator is responsible for what – there is legislation involved – for Government potentially; there are professional standards for the GPhC and there are NHS contractual requirements for PSNC to negotiate and NHSE&I to manage;
 - g) Business contract matters should not be part of or managed by the NHS contractual arrangements? (Point 4 in the asks attached as an annex answered)
 - h) Where does supervision of the supply occur in the process and what are the responsibilities of the two superintendent pharmacists involved?
 - i) The interoperability of IT and operating systems is both a safety and commercial issue and relevant to fairness – how this this issue be addressed.
 - j) change management for smaller businesses without relevant resources
14. The report of the CCA roundtable meeting was noted and that the report of the NPA roundtable meeting was not yet public.

Action 2

- 15. The issues to be considered by committee in September, before being raised with DHSC.**

Regulations and Terms of Service

16. The subcommittee noted the paper and was informed that other regulation changes regarding Healthy Living Pharmacies and the Medication Discharge Service were still under consideration and the policy issues had been dealt with by SDS. The proposed change to paragraph 35 of schedule 4 of the Terms of Service was agreed by the subcommittee. It was

suggested that any reasonable requests should be nationally and after agreement with PSNC. The paragraph 18 provision on the provision of electronic information relating to healthy living campaigns was agreed. There was considerable concern at the decision-tree and the possible introduction of onerous and prescriptive requirements around issues of supply shortage. It was accepted that information could be requested by NHSE&I electronically. The issues may be dealt with by LRA and/or NT going forward.

Rural Working Group

17. The report of the recent meeting of the Rural Working Group was noted. Subcommittee noted the EPS issue raised by the group and agreed that it would be helpful for all GP practices including dispensing doctor practices to use EPS; and noted that the issue of postcode sweeps would be raised with NHSE&I at an appropriate time, given current pressures relating to COVID-19 and NHSE&I and DHSC proposals.

The 2019/20 student/pharmacist cohort

18. The subcommittee noted the paper which highlighted the various issues on provisional registration, including the proposed introduction of an interim foundation year. Recent announcements by GPhC and others were noted. It was agreed that funding for the next year should be sought for supporting the 2019/20 cohort – both provisionally registered pharmacists and those remaining as pre-registration students– on the basis of the additional work for contractors as employers supporting their workplace training and time off for study (unless a part time contract is used). It was noted that many of the issues are being dealt with by the Community Pharmacy Workforce Development Group, but funding issues are for PSNC.

Action 3

19. PSNC to continue to seek discussions with NHSE&I on the issue of support for the 2019/20 student/pharmacist cohort.

Transition out of the EU (Brexit update)

20. The report on the renewed preparations for the transition out of Europe at the end of the year was noted and that PSNC had raised the need for DHSC communications on these preparations for patients, prescribers and the public - so that they can have confidence in the arrangements, to reduce the risks of increased prescribing or demand by patients for extra stocks of medicines.

21. The items for AOB were:

Market entry and delay for applications. There was concern that PCSE current delays are significant and not connected with fitness to practice issues which have been ongoing for many months. It was agreed this would be raised with NHSE&I.

Action 4: Raise PCSE delays with NHSE&I

Supply of dispensed medicines from hub registered pharmacy premises.

Concern was raised that there appears to be an example of supply of dispensed medicines from registered pharmacy premises that do not have an NHS contract. This was queried.

Gordon Hockey responded indicating:

- a) The understanding was that this had started (if indeed it was occurring) during the COVID-19 outbreak to assist supply of medicines to patients;
- b) That NHSE&I was aware of the activity and PSNC has had conversations with other contractors on this issue;
- c) For a national supplier, the issues were different to brinks and mortar pharmacies because the location of the pharmacy is not relevant (accepting that some DSPs are not proper national suppliers);
- d) It is know that DHSC favour this model (patient to spoke to hub to patient) in discussion on hub and spoke dispensing;
- e) The PSNC position remains unchanged – in favour of the current legislation – and this is both necessary and appropriate for the support of market entry provisions;
- f) The issues will be explored within PSNC hub and spoke discussions;
- g) PSNC does not usually make complaints against a contractor (but accepting that it will do so to support contractors as a whole if this is considered necessary)

No.	Action	Responsible
Action 1	Keep the subcommittee informed of broad progress in advance of discussion at the committee	GH
Action 2	The issues on hub and spoke dispensing to be considered by committee in September, before being raised with DHSC	GH
Action 3	PSNC to continue to seek discussions with NHSE&I on the issue of support for the 2019/20 student/pharmacist cohort.	GH
Action 4	Raise PCSE delays with NHSE&I	GH

Appendix 02/09/2020

Subject	NHS Amendment Regulations
Date of meeting	7 September 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential
Overview	To consider additional NHS regulations and Terms of Service including new COVID related provisions
Proposed action(s)	To agree the changes – these are set out in the paper. The draft regulations are for reference only
Author(s) of the paper	Gordon Hockey

The provisions are as follows and questions for the LRA are in bold (the numbers at the beginning of each subparagraph relate to the paragraph of the regulation in the SI):

- a) 3. If a contractor enters administration notice must be given.

Agreed already

- b) 4. commencement of notice with at least 30 days' notice, but a change to the opening date can be made at a later date; NHSE&I can agree a shorter period of notice.

Agreed already

- c) 6 and 7 **Pandemic Treatment Protocol (PTP)** introduce an additional aspect to the essential dispensing service similar to the provision for Serious Shortage Protocols – activated when required. If a contractor receives an electronic message through a secure service that orders the supply of drugs in accordance with a PTP and a person is entitled to such supply (it is envisaged that a patient would come to the pharmacy and present a unique validation code). The pharmacy must supply the medicine with reasonable promptness, or give an estimate of when supply can be made and paragraph 8 of schedule 4, subparagraphs 5-10, apply to these PTP supplies (national formulary, quantity, strength or dosage not stated, minimum pack size, special container and original pack). 8(b) There are also relevant provisions for refusal to supply under a PTP, including where supply is contrary to the pharmacist's clinical judgement.

Is this agreed? A recommendation for Committee

- d) 8 '**Decision tree**' now for EPS – this is now stated on the basis that:
Schedule 4, paragraph 9, 2A - P may refuse to provide a drug or appliance ordered on an electronic prescription if the access that P has to the Electronic Prescription Service is not such as to enable P to dispense that prescription promptly (or at all)...[The proposed addition is] but where P does, P must take all reasonable steps to ensure the product ordered by the prescriber is supplied within a reasonable timescale, which may require (depending on what steps or combination of steps the circumstances require) ' – there then follows a list of activities – providing to the patient with details of local pharmacies which may be able to supply, urgent supply with Rx, urgent provision of a non-electric Rx and arranging delivery or for later collection by the patient's representative.

This is not the same as previous proposals and the actions are required where there is no access to EPS, NOT where a single product cannot be supplied. This is broadly equivalent to PSNC guidance on EPS failures <https://psnc.org.uk/wp-content/uploads/2013/07/EPS-How-to-manage-EPS-technical-failures-Factsheet.pdf>

Is this agreed? A recommendation for Committee

- e) 9 It is confirmed that owings may be in electronic form and the requirement to undertake training on repeat dispensing is deleted.

Already agreed

- f) 10 Relevant changes because EPS is being made mandatory for NHS pharmacies

Agreed already

- g) 11 Health campaigns – considered and agreed at the last LRA meeting
- h) 12 Discharge Medication Service – PSNC comments are included in the draft. Agreement is led by SDS - agreement of the service specification with the regulations.
- i) 13 **Flexible provision of relevant immunization services during a pandemic** – essentially this allows NHSE&I to agree, on application, a specified period within a pharmacy's core or supplementary hours when limited pharmaceutical services may be provided, for example when only flu vaccinations might be given. For coronavirus and flu NHSE&I may give a general notice of what is permitted.

Is this agreed?

- j) 14 Changes to the clinical governance provisions to introduce healthy living pharmacy provisions from PQS to the terms of service. Work led by SDS.
- k) 15 consultation rooms and similar arrangements – also includes provisions for DSPs to be healthy living pharmacies. Led by SDS. Bricks and Mortar pharmacies not currently with a consultation room have until 1 April 2023 to introduce one. There are exceptions for premises are too small to have one. DSPs will also be required to have a website, not unreasonable for a national provider of services. Work led by SDS.
- l) 16 accessing summary care records – terms are revised; access must be constant and reliable during core and supplementary hours, so far as that is within the contractor's control.

Agreed already

- m) 17 EPS is made mandatory for NHS pharmacies and access must be constant and reliable during core and supplementary hours, so far as that is within the contractor's control.

Agreed already

- n) 29 Internet access, e-mails and profiles – At least 2 pharmacy staff must have live links to the NHS shared mail address (unless fewer than 2 members. Staff including locums must have access. Comprehensive and accurate DoS profile and NHS website entry required, and each must be verified quarterly. Up to date CAS registration required (initial input of pharmacy e-mails by NHSE&I) that must be monitored with sufficient frequency to ensure the safe and effective supply of medicines and pharmacy must act on alerts, as appropriate.

Agreed already

- o) **18 facilitating remote access.** If a pharmacy decides to provide pharmaceutical services by remote access (this applies to all DSPs and B&M pharmacies on a patient basis, the pharmacy must, to a reasonable extent, facilitate the provision of pharmaceutical services to the patient. And must establish, maintain, and keep under review procedures to facilitate that remote access.

Is this agreed?

- p) 19 inspections and access – considered and agreed by LRA at its last meeting.

The draft regulations (the COVID provisions) in redacted form are attached separately for reference.

Appendix 03/09/2020

Subject	Consultation on proposed changes to the Human Medicines Regulations related to COVID-19 and flu
Date of meeting	7 September 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential
Overview	Revised regulations are proposed to assist the response to the COVID-19 outbreak and flu vaccination programme
Proposed action(s)	To consider key points to make in response to the proposals
Author(s) of the paper	Gordon Hockey

- 1 Government consultation is at <https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments->

[for-covid-19-and-flu](#) As part of the consultation, the Government proposes that changes to the Human Medicines Regulations should:

- a) Provide exemptions from the need for wholesale dealers licences for the supply of a medical product used for the vaccination or immunisation of coronavirus or influenza virus, subject to certain conditions
 - b) Authorise wholesale supplies to any person who may administer a POM by virtue of a protocol relating to coronavirus and influenza virus, subject to conditions;
 - c) Provide conditions for temporary authorisation of medicines, subject to conditions;
 - d) Expand the scope of Patient Group Directions (PGD) (**including those for pharmacy**) to include unlicensed vaccines;
 - e) Provide for the supply and administration of coronavirus and influenza vaccination or immunisation in certain occupational health schemes, subject to conditions;
 - f) Provide that other persons (**which could include pharmacy technicians**) may administer a coronavirus and influenza vaccinations;
 - g) Revise the provision relating to supply in the event of a pandemic (supply of a POM without a prescription);
 - h) Introduce protocols relating to administration of coronavirus and influenza vaccinations – in broad terms condition A - is or is an imminent pandemic and serious risk or potentially serious risk to human life, B - supply or administration is in accordance with a protocol approved by the SoS or appropriate Minister in the devolved countries, C - protocol specifies persons to administer, process by which classes of person of a specified class is designated to administer, recording of administration requirements; D - appropriate temporary or permanent marketing authorisation
 - i) Allow advertisements and promotional material of temporarily approved medicines in related specified circumstances;
 - j) Provide that temporarily approved medicines may be classified as POM or a product that is only available from a pharmacy.
- 2 The provisions give the Government considerable flexibility for its national vaccination or immunisation against coronavirus and influenza virus.
- 3 Practical steps DHSC is taking to prepare for vaccination or immunisation for coronavirus include an 'Expression of Interest' <https://ted.europa.eu/udl?uri=TED:NOTICE:350824-2020:TEXT:EN:HTML> - and provisions in the essential dispensing service for all NHS pharmacies (the earlier paper). While the expression of interest may be of concern, because after a business case has been established, it can be a precursor to a tender, it is reasonable for a Government to consider all options as it prepares for an exercise of this scale. DHSC is continuing to include PSNC in its coronavirus vaccination planning and

considering the involvement of all community pharmacies and has asked PSNC to consider and offer the costs for a community pharmacy service/protocol. There are other considerations including capacity to provide vaccinations.

Question for LRA

- 4 It is suggested that PSNC should support the proposals and indicate that the BAU - medicine supply chain and administration of any coronavirus vaccine by community pharmacy - offer more reliability and established patient safety on vaccinations and also, that patients and the public will naturally turn to those from whom they obtain medicines and advice and who are readily accessible on the High Street.

...