

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee Agenda

For the meeting to be held on Wednesday 25 February 2020

At 14 Hosier Lane, London EC1A 9LQ

1 – 1.30pm in the Southgate Room

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 November 2019 ([Appendix 01/02/2020](#)).
5. Matters Arising

Action

6. Hub and spoke dispensing between legal entities(confidential) ([Appendix 02/02/2020](#))
7. Supervision (confidential) ([Appendix 03/02/2020](#))
8. Violence in pharmacy (confidential) ([Appendix 04/02/2020](#))
9. Provider Assurance – OOPE (confidential) ([Appendix 05/02/2020](#))
10. GPhC consultation on pharmacy fees (confidential) ([Appendix 06/02/2020](#))
11. GPhC consultation on MDS (confidential) ([Appendix 07/02/2020](#))

Report

12. Brexit update (open) ([Appendix 08/02/2020](#))
13. Medicines and Medical Devices Bill (confidential) ([Appendix 09/02/2020](#))
14. Regulation and competition (confidential) ([Appendix 10/02/2020](#))
15. Any other business

Pharmaceutical Services Negotiating Committee Legislation and Regulatory Affairs Subcommittee

Minutes of the Legislation and Regulatory Affairs Subcommittee meeting on 27 November 2019.

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

In attendance: Gordon Hockey, Peter Cattee, David Broome, Adrian Price, Tricia Kennerley, Has Modi, Mark Burdon, Mike Dent and Rob Thomas.

Apologies: There were no apologies for absence.

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

Minutes: The minutes of the meeting on 4 September 2019 were approved and the actions discussed briefly.

Consolidations and prescription direction

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Dispensing/delivery models and hub and spoke dispensing between legal entities and DSPs –ongoing initial consideration

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Matters of Report

Brexit update

- 3.1 The subcommittee noted the report and that DHSC had issued the first 3 Serious Shortage Protocols. There was comment that when DHSC extend SSPs, it should revise the date on the formal SSP document.

Technology forum

- 4.1 The subcommittee noted the report of the Technology forum's first meeting.

Consultation on needs-based regulation in Wales

- 5.1 The subcommittee noted the report and the proposed needs-based market entry system for Wales.

Regulation of professionals including the pharmacy team

- 6.1 The subcommittee noted the report.

Government/NHS proposals for legislation – Supporting the NHS

- 7.1 The subcommittee noted the report.

Primary Care Support England update

8.1 The subcommittee noted the report.

Any other business

9.1 The subcommittee considered additional terms of service and regulatory changes proposed by DHSC (document tabled at the meeting) as follows:

- a) NHSmail shared mailboxes for every community pharmacy linked with personal NHS mail accounts for pharmacy staff – noted this was agreed as part of the 5-year deal;
- b) Access to the summary care record - noted this was agreed as part of the 5-year deal;
- c) Updating as necessary community pharmacy profiles for NHS 111 directory of services (DoS) - noted this was agreed as part of the 5-year deal;
- d) Keeping profile of NHS.UK up to date and evidence checking this quarterly - noted this was agreed as part of the 5-year deal;
- e) EPS to become mandatory - noted this was agreed as part of the 5-year deal;
- f) Safeguarding level 2 for all pharmacy professionals – discussed in SDS;
- g) All pharmacies to become HLPs – discussed in SDS and negotiations ongoing;
- h) Notification of a contractor going into administration to be included in the regulations – agreed in principle by the subcommittee;
- i) Contract management: access to a list of documents agreed with PSNC that contractors would be required to send to NHSE on request – data to be submitted electronically - agreed in principle by the subcommittee;
- j) Updated CPPQ – subcommittee considered that CPPQ is no longer necessary (noted that this is an approved particular, not within the regulations directly);
- k) Notice of commencement submitted by the contractor earlier than 14 days – agreed in principle subject to a contractor being able to change the exact date of opening nearer the proposed opening date;
- l) Data sharing on campaigns – requires further discussion, not agreed; and,
- m) MHRA CAS system notification of contractor e-mail address – should use shared contractor e-mails NHSE has already and not additional information such as mobile telephone number.

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Appendix 06/02/20

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Appendix 07/02/20

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Appendix 08/02/2020

Subject	Brexit Update
Date of meeting	5 February 2020
Committee/Subcommittee	LRA
Status	Open
Overview	Report
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Report

1. A copy of the note of the most recent Community Pharmacy Brexit Forum meeting is attached as annex A.
2. At the time of writing in late January 2020, it appears to be clear that Brexit will happen on 31 January 2020, but its real affects will not be apparent until 2021 because of the transitional period until 31 December 2020.
3. It remains to be seen what will happen towards the end of 2020, although it seems likely, at least at the current time, that there will still be a potential legal default of a new no-deal Brexit after the end of the transition period.
4. Some of the arrangements and plans made to date, for example, for workforce planning and continuity of supply will be relevant at the end of 2020 and the beginning of 2021. Some arrangements and plans may have to be reused or adapted.
5. The next meeting of the Community Pharmacy Brexit Forum will be as and when required.

Note of the Community Pharmacy Brexit Forum Meeting

7th January 2020 at PSNC, 14 Hosier Lane

Introduction

1. The discussions at the two previous meetings were noted; some attendees were present in person and some on the phone.

Discussion of issues approaching Brexit deadline and issues related to any likely contingency planning during 2020

2. Contingency planning still the same for contractors for the time being despite the changed political landscape. Preparing for no deal BREXIT is legal default. The suggestion was not to change Brexit information until there is official confirmation of a changed approach or until after the legal default of 31 January has passed.
 - It was noted that any contingency planning for the next legal default is yet to be decided and is likely to be determined after Government assessment of the risks (anything subsequent to the Yellowhammer assessment) and following discussions with manufacturers.
 - The forum agreed that the sector's approach should be to ensure continuity of medicine supply to patients and that any risks to that should have appropriate contingency planning.

Discussion of Guide to managing medicines supply and shortages, by DHSC and NHS England and Improvement, published November 2019

3. The forum agreed that it is a very useful document to be used going forward, setting out the business as usual position – with various additions and gaps filled as the issues were explored and documented during the process of producing the Guide.
4. Also noted that arguably there should be complementary 'upstream work' to consider the causes of shortages, in addition to the work to manage shortages when they occur.

Serious Shortage Protocols

5. Now there are two SSPs being used in community pharmacy in England (Haloperidol and Fluoxetine) and the issues identified to date are to do with endorsements and thus payment for contractors; and the relatively low usage of SSPs. Also noted was:
 - In Wales the first SSP is in place – for Haloperidol;
 - The legislation for SSPs is in place for NI and Scotland but there have been no SSPs yet;
 - SSP are significant work and effort to prepare and implement for the Department and the sector
 - The application of a volume medicine SSPs is the real test and would allow better analysis.
 - DHSC will undertake an annual review of the SSP legislation and the use of SSPs.

Communication issues

There were no additional issues noted.

AOB and next dates

It was agreed that the next meeting would be when required.

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