

## PSNC Legislation and Regulatory Affairs (LRA) Subcommittee Agenda

For the meeting to be held on Wednesday 6th February 2019

At 14 Hosier Lane, London EC1A 9LQ

Commencing at 10.30 in the Southgate Room

**Members:** Ian Cubbin (Chair), Jas Heer, Has Modi, 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 October 2018 (pages 2-5) ([Appendix 01/02/2019](#)).
5. Matters Arising

### Action

6. LRA priorities for 2019 (pages 6-7) ([Appendix 02/02/2019](#))
7. Community Pharmacy Provider Companies (pages 8-10) ([Appendix 03/02/2019](#))
8. ....
9. Brexit, Serious Shortage Protocols draft legislation (pages 15-24) ([Appendix 05/02/2019](#))

### Report

10. ....
11. ....
12. ....
13. Data Security and Protection Toolkit (pages 35-37) ([Appendix 09/02/2019](#))
14. RPS Professional Standards for community pharmacy (pages 38-39) ([Appendix 10/02/2019](#))
15. ....
16. Any other business

## Pharmaceutical Services Negotiating Committee

### Health Policy and Regulations / Legislation and Regulatory Affairs Subcommittee

Minutes of a Meeting of the Health Policy and Regulations / Legislation and Regulatory Affairs Subcommittee held at 15.30 on 9 October 2018

Members: Ian Cubbin, Stephen Thomas, Janice Perkins, Jas Heer, Has Modi.

In attendance: Mark Burdon, Peter Cattee, Simon Dukes, Mark Griffiths, David Hamilton, Gordon Hockey, Andrew Lane, Garry Myers, Tricia Kennerley, Sunil Kochhar, Zoe Long, Indrajit Patel, Prakash Patel, Adrian Price, Faisal Tuddy, Gary Warner, Marc Donovan, Sam Fisher, Fin McCaul, Lucy Morton-Channon, Indrajit Patel, Jay Patel, Umesh Patel, Sian Retallick.

Apologies: There were no apologies from subcommittee members.

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

....

....

....

#### Item 4 – ‘Apps’ confidential until the questions are included in DAC2

4.1 The subcommittee and committee members present agreed with the proposed questions, as entry questions for the NHS apps library (in addition to the new DAC2 questions). It was also suggested that the location of the pharmacy should be prominent in the app and made available to the patient before any decision to nominate a dispenser/community pharmacy.

4.2 Concern was expressed at a CCG recommending one app for connecting patients to community pharmacies – paying for the first year of its use. It was agreed that patients should have a choice of which app to use, subject to its use by the community pharmacy of their choice.

4.3 Action: Continue discussions with NHS Digital on gateway questions for pharmacy apps wishing to be listed in the NHS apps library.

## Item 5 – Reports

5.1 The items of report were noted: EPS Phase 4 draft regulations; PSNC's response to the Department of Health and Social Care's consultation on the role of the superintendent and responsible pharmacist; and PSNC's submission to the House of Lords Select Committee on the rural economy.

## Item 6 - Any other business

A relatively inexperienced practice pharmacist proposing to be the superintendent pharmacist of a Distance Selling Premises connected to a GP practice was brought to the attention of the subcommittee. The potential conflicts of interest were noted as well as concern that such a DSP might not meet the ongoing requirements for DSPs set out in the 2013 NHS Regulations.

## Date of next meeting

The date of the next Committee meeting is 13 November 2018 and the date of the next subcommittee meeting is subject to the Committee's discussion on new ways of working at its meeting tomorrow.

List of Actions:	Relevant person(s)
1.5 Action: Respond to the current Health Select Committee Inquiry and continue the work of the Community Pharmacy Brexit Forum.	ZL and GH
3.5 ....	GH
4.3 Action: Continue discussions with NHS Digital on gateway Questions for pharmacy apps wishing to be listed in the NHS apps library.	GH and DA

Subject	LRA priorities for 2019
Date of meeting	6 February 2019
Committee/Subcommittee	LRA subcommittee
Status	Open
Overview	The paper sets out suggested priorities for the subcommittee for 2019
Proposed action(s)	Consider and, with any amendment, agree the priorities
Author(s) of the paper	Gordon Hockey

## Introduction

This paper sets out the priorities for 2019, based on ongoing work, additions from the Committee's planning discussions in November 2018 and wider developments relevant to community pharmacy.

## Priorities include

1. Identifying and considering issues relevant to Brexit, in particular, a no-deal Brexit; and support the work of the Community Pharmacy Brexit Forum.
2. Support consideration of regulatory issues associated with funding, for example, the Pharmacy Access Scheme and Quality Payments.
3. Discuss with Government options for community pharmacy hub and spoke options and respond to any relevant Government proposals, including any on pharmacy supervision.
4. Consider new and emerging technologies in community pharmacy; and support the work of a new Community Pharmacy Technology Forum.
5. Explore regulatory issues associated with local commissioning.

6. Consider and agree a revised model provider company model to be made available to LPCs; and consider how these may work with emerging NHS structures.
7. Contribute to implementation of the recommendations from the statutory review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, seeking to ensure that patients' choice of pharmacy is respected.
8. Ensure appropriate consideration of issues relating to pharmacies in rural areas.
9. Advise and support contractors and LPCs, as appropriate.
10. Consider and advise on regulatory issues involving IT and data/information, the General Data Protection Regulation (GDPR) and the Data Security and Protection (DSP) Toolkit.

(Appendix 03/02/2019)

....

....

Subject	UK exit from the EU (Brexit)
Date of meeting	6 February 2019
Committee/Subcommittee	LRA subcommittee
Status	Open
Overview	There is ongoing work associated with Brexit on policy and communications and the subcommittee is asked to consider the reports and advise as appropriate.
Proposed action(s)	The subcommittee is asked to review any proposed changes to the Terms of Service associated with SSPs (to follow) and consider the work of the Community Pharmacy Brexit Forum.
Author(s) of the paper	Gordon Hockey

## Introduction

There is considerable ongoing work associated with Brexit and the Committee submitted comments for PSNC's response to the consultation on Serious Shortage Protocols. Tomorrow, the Committee will consider:

- Any issues arising from DHSC's Operational Readiness Guidance, which applies to contractors;
- the implementation issues for SSPs, building on the issues identified in the response to the consultation and following further discussions with DHSC on 30 January 2019; (PSNC comments on the proposed legislation and implementation issues are at <https://psnc.org.uk/wp-content/uploads/2018/12/PSNC-response-to-the-consultation-on-urgent-changes-to-the-HMRs-2012.pdf> )
- identify potential issues associated with medical devices
- Pharmacists from community pharmacy to assist DHSC Brexit work (e.g. secondments from the sector)
- Comms' messages to community pharmacy and patients

Comms' work associated with Brexit is being considered by the Communications and Public Affairs subcommittee.



The subcommittee is asked to review any proposed changes to the Terms of Service associated with SSPs and consider the work of the Community Pharmacy Brexit Forum.

## Issues include

### Serious Shortage Protocols

The draft legislation (attached as Annex A) has been laid in Parliament – negative procedure – and should be in place on 9 February.

Broadly, the draft legislation accepts the suggestions put forward by PSNC.

### Flow of information to and from CP

The command structures from DHSC and within NHSE (and involving others) that reach to community pharmacy to provide relevant information in the event of a no-deal Brexit will be essential.

The command structures are being developed by DHSC and NHSE and Bruce Warner, Deputy Chief Pharmaceutical Officer, indicated that he is working on this and will provide details as soon as he can, which he said is likely to be before mid-February.

PSNC has indicated that it and the LPCs can assist with communications to contractors and helping to identify problems as they emerge. The community pharmacy Brexit forum will have a place too; as will its parallel community pharmacy comms group.

Access to the list of NHSmail accounts for community pharmacy will become increasingly important for NHSE and would also be helpful for PSNC and LPCs. NHSE are seeking to obtain the list from NHS Digital for its and our use.

### Terms of Service

These need revision with the introduction of SSPs, since there may be no supply or no complete supply of a medicine against an NHS prescription - the contractor may not make the (full) supply with reasonable promptness.

There are other issues including professional issues such as record keeping and liaising with GPs; and reimbursement and remuneration issues.

PSNC has a meeting with DHSC to discuss these issues on 29 January.

**It is hoped to have draft changes to the regulations to circulate to the subcommittee in advance of the meeting.**

**Shortages and concession pricing** – there's a need to ensure that the concession pricing mechanism supports contractors during any no-deal Brexit. The costs of the manufacturers' six-week stockpile and use of alternative routes and other measures are likely to be reflected in an increased cost of medicine – for generics this is likely to increase the number of concession lines. It is important for continuity of supply that the concession pricing system is as robust as it can be for as long as possible.

An issue for contractors is a medicine for which there is an imposed concession price that is substantially lower than the market price. Although concession prices will never be generous (to maintain downward pressure on the market) and the Margin Survey addresses the issues for the sector as a whole in due course, individual contractors can lose out if they dispense more of such products.

**Community Pharmacy Brexit Forum.**

The November meeting notes and the January Agenda are attached for information as annex C.

**Any comments or observations are welcome.**

[NB: The legislation underpinning FMD is the main part of the SI in which the provisions on SSPs occur.]

**Insertion of regulation 226A (sale etc by a pharmacist in accordance with a serious shortage protocol)**

9. After regulation 226 (emergency sale etc by pharmacists: pandemic disease), insert—

**“Sale etc by a pharmacist in accordance with a serious shortage protocol**

**226A.—**

(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.

(2) Condition A is that the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol (SSP).

(3) Condition B is that the requirements of the SSP are satisfied in respect of to whom, and subject to what conditions, the prescription only medicine may be sold or supplied for the purpose of being administered.

(4) Condition C is that the sale or supply of the prescription only medicine is by or under the supervision of a pharmacist who is of the opinion, in the exercise of his or her professional skill and judgement, that—

(a) in a case to which paragraph (5)(b)(i) applies, the sale or supply of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form of the prescription only medicine ordered by the prescriber is reasonable and appropriate; or

(b) in a case to which paragraph (5)(b)(ii) applies, the sale or supply of—

(i) a prescription only medicine other than the prescription only medicine ordered by the prescriber is reasonable, and

(ii) the substituted prescription only medicine, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this regulation, a SSP is a written protocol that—

(a) is issued by the Ministers (either of them acting alone or both of them acting jointly) in circumstances where the United Kingdom or any part of the United Kingdom is, in the opinion of the Ministers (either of them forming the opinion alone or both of them forming the opinion jointly), experiencing or may experience a serious shortage of a prescription only medicine or prescription only medicines of a specified description;

(b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP—

(i) of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form ordered by the prescriber, or

(ii)of a prescription only medicine other than the prescription only medicine ordered by the prescriber;

(c)provides, in a case to which sub-paragraph (b)(ii) applies, that the other prescription only medicine is to be—

(i)a generic version of the prescription only medicine being substituted, or that both products are generic versions of another prescription only medicine,

(ii)in the case of a biological medicinal product, a similar medicinal product to the prescription only medicine being substituted, or that both products are similar medicinal products to another biological medicinal product, or

(iii)a prescription only medicine that has a similar therapeutic effect to the prescription only medicine being substituted; and

(d)specifies the period for which, and the parts of the United Kingdom (which may be all of the United Kingdom) in which, the protocol is to have effect.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol issued under this regulation has effect, the Ministers must—

(a)review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b)set out the conclusions of the review in a report; and

(c)publish the report.”.

....

## Community Pharmacy Brexit Forum

Draft agenda for the meeting at 10 - 12 noon on Tuesday 22 January 2019  
at PSNC 14 Hosier Lane, London EC1A 9LQ

1. Minutes of the last meeting (to follow)
2. Update on manufacturers' 6-week stockpile and alternative routes for import (DHSC)
3. DHSC Operational Readiness Guidance (DHSC – perhaps from the DHSC Operational Response Centre) PSNC Briefing note attached
4. Practical issues with manufacturers' use of quotas and obtaining unlicensed medicines on a named patient basis (e.g. if unlicensed medicines are imported from non-EU countries) (Discussion)
5. SSPs – an update and discussion of implementation issues (DHSC and discussion) PSNC response to the SSP consultation attached (final legislative provisions to follow)
6. Pharmacists from Community Pharmacy to assist DHSC Brexit work – what is DHSC's request (e.g. details of the job descriptions and work to be undertaken and how this might work practically e.g. secondments) (DHSC)
7. MHRA summary explanation on how medicines, medical devices and clinical trials would be regulated if there's no Brexit deal – with discussion (DHSC/MHRA?)
8. AOB

....

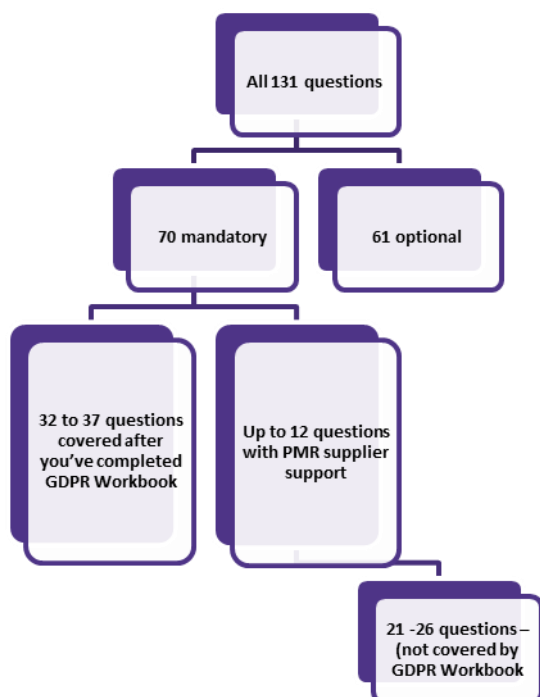
....

....



Subject	Data Security and Protection Toolkit
Date of meeting	6 February 2019
Committee/Subcommittee	LRA subcommittee
Status	Open
Overview	To note the guidance provided to contractors and its link to earlier work on GDPR.
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

**PSNC Briefing 064/18: Completing the Data Security and Protection Toolkit: Overview** – is broadly as follows:



## Background

Contractors are required to give information governance assurances to the NHS each year via an online self-assessment now called the Data Security and Protection Toolkit<sup>1</sup>. The Toolkit questions have been updated to incorporate the General Data Protection Regulation (GDPR) and the National Data Guardian's Ten Data Security Standards for the healthcare sector.

## **Six steps to complete the Toolkit**

### **1. Register for the Toolkit and login**

First register on the Toolkit registration page so that you can complete it before the 31st March 2019. You will need an email address (NHSmail or otherwise), your ODS (F) code, and a few minutes for the registration process. Once you have obtained your login credentials, use these to login to the Toolkit.

### **2. Enter information into your Toolkit 'Organisation Profile' webpage**

- a) Confirm whether you completed Community Pharmacy GDPR WB Part 3 (GDPR Workbook). PSNC led the cross-sector Community Pharmacy GDPR Working Party and produced GDPR guidance. If you did complete the workbook, then 32 to 37 of the 70 mandatory questions will be automatically marked as 'completed'.
- b) Confirm who your Data Protection Officer (DPO) is. PSNC recommends an internal DPO for their local knowledge but the reasoning for staff selection and any later conflicts can be noted as per advice.
- c) Confirm that NHSmail is the only email system you use to transfer patient information so that two Toolkit questions about email may be automatically marked as 'completed'.
- d) Confirm if you have a Caldicott Guardian (not mandatory).

### **3. Select your PMR supplier within the Toolkit**

Cegedim, EMIS, Positive Solutions and RxWeb advised PSNC and NHS Digital that they will support contractors (if you select your PMR supplier within the Toolkit) by bulk-adding text after NHS Digital have added the feature (planned: February 2019 and it is expected after the 'batch submission' mentioned in step 5 below) to assist with up to 12 technical mandatory questions. If you want to add more detail to PMR text that 'auto appears' after your selection, you can. Your supplier won't be able to view any of your answers.

### **4. Consider whether all staff have had appropriate training**

Toolkit question 3.3.1 says: "Staff pass the data security and protection mandatory test... Level 1 Data Security Awareness training" but equivalent training is acceptable. NHS Digital has confirmed to PSNC that the question can be marked completed if equivalent training has taken place including the GDPR guidance for Community Pharmacy (Part 2) staff training booklet. Most contractors will already have

18

trained all staff to this level during the GDPR implementation period which began in May 2018. If not, you must ensure 95% of all current staff have been trained.

#### **5. Consider whether your pharmacy organisation will use the Toolkit 'batch submission' feature**

Pharmacy organisations with four or more branches may wish to use the Toolkit 'batch submission' feature to do a single submission. You can register and begin completion of a 'master' head office submission. The 'batch' feature is in the advanced testing phase and planned for release early in 2019, well before the March deadline. Further guidance can be found at: [psnc.org.uk/igfaqs](https://psnc.org.uk/igfaqs)

#### **6. Visit the Toolkit Assessment section and use PSNC's guidance to assist completion of remaining mandatory questions**

Click into the 'Assessment' section of the Toolkit and use the filtering options on the top-left of the screen, to display just the mandatory questions so that it is easier to enter answers. The 'optional' questions do not require completion.

**Toolkit: Question-by-question PSNC guidance (doc version, mandatory questions) and**

**Toolkit: Question-by-question PSNC guidance (spreadsheet version, all questions): - provide guidance on the remaining questions.** Work your way down the Toolkit questions from top to bottom completing the mandatory questions not already marked as completed. It is a contractor's decision as to whether to include sensitive information within their answers. Where your PMR has supplied information for a technical question, you may add more information, if needed.

Subject	RPS Professional Standards for community pharmacy
Date of meeting	6 February 2019
Committee/Subcommittee	LRA subcommittee
Status	Open
Overview	<p>To note PSNC involvement with the RPS Community Pharmacy Standards Sector Wide Group.</p> <p>The sector wide group had the first of its 3 meetings – broadly, PSNC representatives welcomed the initiative but indicated the standards would need to be considered once drafted; and cautioned about adding additional cost, by raising standards unnecessarily, at a time of funding cuts for the sector.</p> <p>The RPS Steering Group’s terms of reference are attached for information</p>
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

## Background

The Royal Pharmaceutical Society (RPS) publishes professional standards, developed by the profession, that describe good practice, systems of care and working in pharmacy. RPS professional standards are supportive and enabling whilst also professionally challenging, describing and building on good practice to support pharmacists to achieve excellence in professional practice and to deliver high quality care.

The first RPS Professional Standards for Community Pharmacy Services will describe best practice in community pharmacy services for patients and the public, using a patient centred approach to describe “what good looks like”.

The RPS will develop and publish the standards, in accordance with the RPS [process](#) for the development of professional standards and guidance which is accredited by the National Institute for Health and Care Excellence. We will engage with a wide range of stakeholders across Great Britain, including patients and patient groups, throughout the development of the standards. The draft standards will be published for open consultation providing opportunity for comment before the standards are finalised and published.

The standards will reflect the current evidence base, health and social care organisational structures, professional requirements and user needs for community pharmacy services. We aim, in the development of these standards, to build on experience and expertise from across England, Scotland and Wales and to complement existing guidance and standards.

## **Purpose of the Steering Group**

The independent steering group will work closely with the RPS to develop the professional standards and will be chaired by an external independent Chair and Lead Author. The multidisciplinary group will comprise community pharmacists and pharmacy technicians providing services, health professionals interfacing with community pharmacy services, patients and patient groups, and academics.

## **Functions**

- Confirm the scope of the professional standards.
- Support the development of the first draft of the standards based on the literature review and initial scoping.
- Review subsequent drafts of the standards as they are iterated following testing and consultation.
- Support final sign off of the standards.
- Provide support and guidance to the project consultant and lead author.
- Input into strategies to disseminate the professional standards.
- Promote the standards once published.

## **Accountability**

The steering group will provide governance and oversight and will contribute to the development of the standards through constructive and reasoned feedback and advice within the context of the functions described above.

The Royal Pharmaceutical Society will write, edit, and publish the standards considering the advice of the steering group. The final content will be reviewed and sign off supported by the steering group.

## **Duration**

Initial expectations are that the group will exist for twelve months (January 2019 – December 2019)

## **Commitment**

It is envisaged that the group will meet three times in person at RPS London offices. In addition there will be further input by email, webinar and telephone.

## **Membership of the group**

All members are expected to conform to the RPS code of conduct for members of governance bodies as well as codes applicable to their respective disciplines and institutions.

Pharmacist members of the Steering Group will be RPS members.

**Royal Pharmaceutical Society, October 2018**

....