

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee Agenda

For the meeting to be held on Monday 23 November 2020

By Zoom from 10.30 am to 12.00 noon

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 September 2020 ([Appendix 01/011/2020](#))

Action

5. Hospital prescriptions and supplies of certain medicines through community pharmacies ([Appendix 02/11/2020](#))[[confidential paper](#)]
6. Regulatory dispensations sought in response to the second wave of COVID-19 ([Appendix 03/11/2020](#))
7. Twelve-month review of Serious Shortage Protocols ([Appendix 04/11/2020](#))
8. GPhC consultation: Managing concerns about pharmacy professionals: Our strategy for change ([Appendix 05/11/2020](#))

Report

9. NHS amendment Regulations ([Appendix 06/09/2020](#))
10. Brexit ([Appendix 07/11/2020](#))
11. Supply of dispensed medicines from pharmacy premises that do not have an NHS contract ([Appendix 08/09/2020](#))
12. Principles of regulation ([Appendix 09/11/2020](#))
13. Pharmacy Access Scheme ([Appendix 10/11/2020](#))

14. Any other business

Appendix LRA 01/11/2020

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee

Minutes for the virtual meeting held on

Monday 7 September 2020

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

In attendance: David Broome, Mark Burden, Alastair Buxton, Peter Cattee, Simon Dukes, Jas Heer, Gordon Hockey, Tricia Kennerley, Has Modi, Garry Myers (for the last agenda item), Prakash Patel, Sian Retallick, Layla Rahman and Gary Warner.

Welcome from the Chair

1. The Chair welcomed everybody to the meeting.

Apologies for absence

2. There were apologies from Sunil Kochhar.

Conflicts or Declarations of Interest

Minutes of the last meeting

3. The minutes of the subcommittee meeting held on 29 July 2020 were approved.

Actions and Matters Arising

4. There were no matters arising.

NHS amendment Regulations

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Consultation on proposed changes to the Human Medicines Regulations relating to COVID-19 and flu

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AOB

5. There were no AOB items.

No.	Action	Responsible
Action 1	To recommend to the Committee the four changes to NHS regulations considered, with one caveat that delivery should not be referenced in the regulations; and inform NHSE&I	GH
Action 2	Respond to the consultation as agreed and confirm the Government's safety net indemnity insurance will cover contractors supplying and administering vaccines as part of an NHS pharmaceutical service – a Pandemic Treatment Protocol – under section 247A of the Human Medicines Regulations 2012.	GH

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Subject	Regulatory dispensations sought in response to the second wave of coronavirus
Date of meeting	23 November 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential [no longer]
Overview	Consideration of the regulatory dispensations that have been sought and should be sought
Proposed action(s)	Should PSNC seek additional regulatory dispensations?
Author(s) of the paper	Gordon Hockey

- 1 Various regulatory dispensations have been sought to assist contractors facing workload and staffing pressures during the second wave of coronavirus in a paper provided to NHSE&I (and DHSC).
- 2 The full paper has been circulated to the Committee.
- 3 The regulatory dispensations sought in the paper are in Annex A below.
- 4 Should PSNC seek additional regulatory dispensations?

Regulatory dispensations sought

1. The regulatory dispensations already agreed in principle should be implemented.
 - waive the NHSE&I determined Clinical Audit (in favour of voluntary completion of the HEE workforce survey)
 - suspend or delay the requirements around the DSP Toolkit (PSNC has asked for delay until March 2022),
 - suspend or delay the Community Pharmacy Patient Questionnaire (PSNC has asked that this is waived) and
 - suspend or delay the Pharmacy Audit (PSNC has asked that this is waived).

2. In addition, the following is asked:
 - a) **Contractors are given more time to complete PQS part 2 and, at the same time, PQS 2021/22 delayed – both by 6 months. The remuneration associated with PQS Part 2 work (2020/21) should be paid to contractors in this financial year, in accordance with the expectations of the CPCF; and payments for next year (2021/22) should include appropriate arrangements for an aspiration payment in the first half of the year.**
 - b) There is a national announcement on closed-door working as at the start of the pandemic (this has been requested already);
 - c) There is a national announcement in relation to opening hours during which only flu vaccinations (and coronavirus vaccinations) may be provided (no other pharmacy services), and this includes, where desired by contractors, the option for any additional supplementary hours.
 - d) Contractors are asked to prioritise patient facing services and given certainty that NHSE&I will not issue breach notices in relation to those contractual requirements that need not be completed.
 - e) Contractors are not required to comply with verification of the NHS Website and DoS entries until further notice (but for the avoidance of doubt must keep these up

to date) and not required to comply with quarterly data obligations or other routine data collection requests by NHSE&I until further notice.

- f) Contractors are given understanding and tolerance in the event of any regulatory failures generally, including any associated with the regulations that came into force on 9 November 2020 (including (e) above if not specifically waived until further notice); and no remedial, breach or other notices are issued to contractors (other than those involving patient safety issues or material loss to the NHS) until further notice; for example, if early closures are necessary due to staff fatigue.
 - g) Contractors receive a flexible and understanding approach on their reimbursement and remuneration claims to ensure payment is made for relevant work undertaken, so, for example, claims that are late, missed or mis-claimed due to COVID-19 related reasons are still paid.
 - h) Community pharmacy provision over the Christmas and New Year period is clarified urgently, and on the basis of estimated demand, and the same fee as earlier in the outbreak (£250 per hour) is confirmed for any nationally directed opening.
 - i) Declaration of an emergency by the Secretary of State is continued in Directions, to extend beyond 30 November 2020, ideally until Easter 2021.
 - j) Further discussions on regulatory dispensations and the prioritisation of pharmacy services continues as the second wave continues.
3. Further, as a matter of urgency, contractor issues with Test and Trace are essential to resolve as set out in the sector's letter to the Minister; a response to the letter is awaited. NHS Test and Trace decision-making remains a significant threat to the continuity of pharmacy services in certain areas. This issue is particularly difficult for smaller contractors which are unable to reallocate resources to affected pharmacies in the same way as contractors with more pharmacies and staff. There are also knock on effects for local contractors – they are already under pressure and receive more workload where pharmacies close, even temporarily.

4. At the NHSE&I webinar yesterday [12 November 2020], representatives of NHS Test and Trace provided reassuring advice and it remains the case, albeit now accepted and authorised by NHS Test and Trace, that community pharmacy contractors should go direct to PHE Local Health Protection Teams to resolve issues which relate to continuity of pharmacy services. **We ask for NHSE&I and DHSC with Public Health England and NHS Test and Trace to develop official guidance for community pharmacy in consultation with PSNC (which could be based on the information provided by NHS Test and Trace at the NHSE&I webinar).**
5. **PSNC also requests regular coronavirus testing of pharmacy staff, to assist with continuity of the community pharmacy NHS services.**
6. Finally, there is a need to make relevant announcements to support pharmacy contractors as soon as practicable.

Subject	Twelve month review of Serious Shortage Protocols (SSPs)
Date of meeting	23 November 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential [no longer]
Overview	The first SSP was issued in October 2019 and the DHSC is now conducting a 12-month review of SSPs
Proposed action(s)	The subcommittee is asked for information and comment to assist a response to the consultation
Author(s) of the paper	Gordon Hockey

- 1 The schedule of SSPs introduced since October 2019 is at Annex A below.
- 2 PSNC guidance on SSPs is at <https://psnc.org.uk/contract-it/brexit-and-community-pharmacy/serious-shortage-protocols-ssps/> and when each SSP has been issued PSNC has issued additional guidance.
- 3 DHSC has indicated that a 12 month review was favoured by Industry. The explanatory notes to the legislation <https://www.legislation.gov.uk/uksi/2019/62/regulation/9/made> indicate that:

“Industry respondents favoured a time limited introduction of the provision for a serious shortage protocol. In response to both concerns, a review clause has been included requiring a review of the serious shortage protocol as soon as is reasonably practical after the end of one year after the first such protocol starts to have effect.

This will look at, specifically, any adverse consequences for either the market in prescription only medicines or patient safety. A stakeholder consultation will be conducted as part of the review. The Department will continue to work closely with suppliers to mitigate the impact of shortages on patients including on the consideration of introducing a serious shortage protocol.”

- 4 In accordance with the review provision in the regulations, DHSC asks for responses to the following questions:
 - a) *Have you had, or been made aware of by colleagues or stakeholders, any concerns about the impact of the Serious Shortage Protocols issued over the past year on the prescription only medicines market?*
 - b) *Have you had, or been made aware of by colleagues or stakeholders, any concerns about the impact of the Serious Shortage Protocols issued over the past year on patient safety?*
- 5 The subcommittee is asked for information and comment to assist a response to the consultation.

Serious Shortage Protocols that have been issued to date

SSP	Alternative	Issued	Ended	Times used	Notes
SSP01 Fluoxetine 10mg capsules	1 x 10mg fluoxetine tablet OR 2.5ml of fluoxetine 20mg/5ml oral solution SF OR 2.5ml of fluoxetine 20mg/5ml oral solution	3/10/19	25/10/19	2,844*	England only. Withdrawn early due to supply improvement
SSP02 Fluoxetine 30mg capsules	1 x 10mg fluoxetine tablet, PLUS 1 x 20mg fluoxetine capsule	3/10/19	18/12/19		England only. SSP was extended from the original end date of 31 October to 20 November and again until 18 December and varied to change the alternative that could be supplied, replacing the option to supply 10mg tablets with 10mg capsules
SSP03 Fluoxetine 40mg capsules	1 x 20mg fluoxetine capsules 2	3/10/19	20/11/19		England only. SSP was extended from the original end date of 31 October
SSP04 Haloperidol (Serenace®) 500mcg capsules	1 x 500 microgram haloperidol tablet	23/12/19	23/3/20	2,065	England and Wales
SSP05 Fluoxetine 10mg tablets	1 x fluoxetine 10mg capsule	12/3/20	In effect. Due to		England, Wales and Northern Ireland. SSP was extended from the original end date of 12/6/20 to 31/3/21

SSP	Alternative	Issued	Ended	Times used	Notes
			end 31/3/21		
SSP06 Fluoxetine 40mg capsules	2 x 20mg fluoxetine capsules	20/5/20	2/10/20		England, Wales and Northern Ireland. SSP was extended from the original end date of 20/7/20 to 2/10/20
SSP007 Fluoxetine 30mg capsules	1 x fluoxetine 20mg capsule PLUS 1 x fluoxetine 10mg capsule OR 3 x fluoxetine 10mg capsules 4	20/10/20	In effect. Due to end 22/12/20		England and Wales
SSP008 Salazopyrin® EN-Tabs 500mg	Sulfasalazine 500mg gastro-resistant (GR) tablet	20/10/20	In effect. Due to end 4/12/20		England and Wales

*Because SSP 01-03 ran simultaneously and because all the alternatives supplied in accordance with the SSPs involved either 10mg fluoxetine tablets or 20mg fluoxetine capsules, it is not possible with the available data to determine exactly which SSP they were supplied in accordance with.

Subject	GPhC consultation: Managing concerns about pharmacy professionals: Our strategy for change
Date of meeting	23 November 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential [no longer]
Overview	Consultation by the GPhC on future strategy
Proposed action(s)	What comments should PSNC make in response to the consultation
Author(s) of the paper	Gordon Hockey

- 1 The consultation can be found at <https://www.pharmacyregulation.org/get-involved/consultations/managing-concerns-pharmacy-professionals>
- 2 Proposed is a new, more flexible approach to managing fitness to practise concerns. The approach follows Right Touch regulation advocated by the GPhC's regulator, the Professional Standards authority, and in summary seeks to promote the following strategic aims as follows
 - **Strategic aim 1: Keeping patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns**
 - To involve more investigation and enquiries, quicker action on serious concerns and a more flexible approach when less serious – such as reflective learning, voluntary agreements, voluntary removal and mediation- and guidance to assist employers with managing and referring concerns.
 - **Strategic aim 2: Taking a person-centred approach that is fair, inclusive and free from discrimination and bias**

- To involve an assessment of needs for those involved in the complaints and fitness to practise procedures, for example identifying those with mental health issues and being fair and inclusive: there are more complaints about BAME registrants and GPhC wants to understand why this is so and ensure there is no unconscious bias in its processes.
 - **Strategic aim 3: Shifting the perception from blame and punishment to openness, learning and improvement**
 - To shift away from punishment and blame, to learning and improvement. Fitness to practise has always been about ensuring only those who should be registered, are registered, but has (understandably) always been considered as punishment to the individual disciplined. But the GPhC knowledge hub is a valuable tool for pharmacy professionals and pharmacy owners.
- 3 Although not stated in direct terms, the new approach has benefits in terms of:
- a) Cost reduction – hearings are expensive, gentler regulatory action less so;
 - b) Reduced impact on pharmacy professionals – not having hearings shortens the process considerably and fitness to practise issues not being addressed in public is helpful to any professional; and,
 - c) Satisfied complainants – complainants rarely want punishment and generally seek recognition of issues and learning – both are better achieved with communication and discussion than with formal legal hearings.
- 4 It is suggested that PSNC endorse the GPhC's proposals.

Subject	NHS amendment Regulations
Date of meeting	23 November 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential [no longer]
Overview	Report
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

- 1 The latest NHS regulations came into force from 9 November, and then over the next 6 months.
- 2 The PSNC office (Alastair and Gordon) published a series of 14 contractor articles on the new regs that have been well received. They are at: <https://psnc.org.uk/contract-it/pharmacy-regulation/changes-to-the-terms-of-service-in-2020/>
- 3 PSNC agreed to publish contractor information before 9 November as NHSE&I continued to work on its own guidance on the new regs, on which PSNC has also been able to comment.
- 4 Until the NHSE&I guidance is published there will be no regulatory enforcement, although the appropriateness of any enforcement during the second wave of coronavirus would be questionable, unless patient safety issues or material loss to the NHS are involved.

Subject	Brexit Forum
Date of meeting	23 November 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Public
Overview	Report
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

- 1 While 'Brexit is done', the risks of a no-deal exit from the EU at the end of the Transition Period (TP) on 31 December 2020 remain similar.
- 2 A PSNC representative attends DHSC continuity of supply meetings and PSNC hosts the now larger Brexit Forum of 50 plus members and virtually all national pharmacy organisations. Most organisations no longer send their CEO.
- 3 There are particular medicine supply issues around the Northern Ireland protocol and contractors with pharmacies in both Great Britain and Northern Ireland should take particular care to be aware of the relevant guidance.
- 4 Key issues in the event of a no-deal are:
 - a) Continuity of supply of medicines and appliances - for which there is considerable work ongoing - see below - PSNC is engaged with this.
 - b) Purchase price of medicines that affect contractors and concession prices and more - we are, through Mike's team, sighted on the issues and these have been

discussed with DHSC previously - the PSNC response to the DHSC consultation highlighted some of the issues back in December 2018 - this is attached (see the general observations on page 6)

- c) Patient and prescriber demand. The former relates as much to confidence in the supply chain as anything else and prescriber demand relies primarily of the actions of doctors - and is primarily a matter for the NHSE&I working together with DHSC. We have had conversations on this with NHSE&I, DHSC and the BMA and a meeting is planned with the BMA to discuss the issues further.
- 5 The most recent e-mail to the Forum which also sets out dates for the next two provisional meetings is as follows:

Dear All

Included with this e-mail are: three main updates, provisional dates for the next CP Brexit Forum meetings and further information:

DHSC update on preparations

Yesterday, DHSC issued an update to preparations for the end of the Transition Period - a copy is attached.

DHSC is holding a webinar at 10:30 this Thursday, 19 November to talk through the main points of the letter and provide a verbal update on the programme. This is aimed at industry but may be of interest to some, particularly those with NI related activities. To join, please register by following this link: <https://www.workcast.com/register?cpak=8916327643279368>

Northern Ireland Protocol

*On issues around the Northern Ireland protocol - **which are important for organisations with any connection with NI, for example, with community pharmacies in NI** - there is more time to work through the issues, although the additional year - to 31 December 2021 - is not a long time. See the new DHSC page on placing manufactured goods on the NI market can be found at: <https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-northern-ireland-from-1-january-2021> Those with wholesale activity and intra pharmacy transfers of medicines into NI should engage with this activity. The DHSC website indicates that:*

The UK and the EU exchanged updates on the implementation of the Protocol. The Committee noted that an agreed approach had been reached on a phased process for implementing medicines regulation in Northern Ireland up to 31 December 2021, providing the additional time needed for businesses to prepare in relation to batch testing, importation and Falsified Medicines Directive requirements. Agreement has also

been reached on the process for identifying Northern Ireland traders for VAT purposes and enabling them to reclaim VAT through existing IT databases when trading in goods with the EU; for transit procedures to be available in Northern Ireland and operate consistently with the Common Transit Convention; and on the elements of the Electricity Directive that will not apply in Northern Ireland.

FMD - latest information

PSNC has issued an update at: <https://psnc.org.uk/our-news/update-on-fmd-for-contractors/> More information for contractors in NI is here: <https://psnc.org.uk/wp-content/uploads/2020/11/20-11-UK-FMD-WG-statement-future-of-FMD-in-Great-Britain-and-Northern-Ireland-FINAL.pdf>

Provisional dates for future Brexit Forum meetings

Provisional dates and times for the next meetings of the forum are **December 14 and January 14, the meetings between 10.30 and 12noon.**

I will let you know nearer the time if the meeting is happening.

Further information

The main page on post Transition Period is at <https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector>.

Guidance for pharmacists - that will take effect if the UK leaves with a no-deal - on prescriptions issued in the EEA and Switzerland guidance is at: <https://www.gov.uk/guidance/prescriptions-issued-in-the-eea-and-switzerland-guidance-for-pharmacists>

For those interested, the page on placing on the GB market (including new unfettered access provisions) can be found here: <https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021>

For those interested, the latest information from the Border and Protocol Delivery Group is also attached.

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Subject	Principles of economic regulation
Date of meeting	23 November 2020
Committee/Subcommittee	Legislation and Regulatory Affairs subcommittee
Status	Confidential
Overview	A brief consideration of pharmacy regulation
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

- 1 Regulation of community pharmacy - individuals and premises - is carried out by the GPhC in accordance with right touch regulation and overseen by the Professional Standards Authority. The principles of Right Touch regulation are:
 - Proportionate: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised
 - Consistent: rules and standards must be joined up and implemented fairly
 - Targeted: regulation should be focused on the problem, and minimise side effects
 - Transparent: regulators should be open, and keep regulations simple and user friendly
 - Accountable: regulators must be able to justify decisions, and be subject to public scrutiny
 - Agile: regulation must look forward and be able to adapt to anticipate change

- 2 The principles of economic regulation are similar and are:
 - Accountability
 - Focus

- Predictability
- Coherence
- adaptability
- efficiency

More details on these principles are in *Principles for Economic Regulation*, published by BIS in 2011, at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/31623/11-795-principles-for-economic-regulation.pdf

- 3 Further relevant information is included in *Economic rationales for regulating markets* published by Parliament's Scrutiny Unit in 2011. This recognises the special status of healthcare.
<https://www.parliament.uk/globalassets/documents/commons/Scrutiny/Rationale-for-regulating-markets.pdf>
- 4 Medicine supply has been identified by the NHS as benefiting from competition whereas, currently, collaboration is preferred in the healthcare sector. While the principles of economic regulation were not written for markets in the healthcare sector, they are of broad relevance to them; recognising that other policy and political considerations apply.
- 5 While there is potentially much of interest to PSNC in the principles of economic regulation, there is much PSNC enjoys that would not be expected in a market regulated by such principles. For example: negotiation and the shared consideration of issues and policy between DHSC and PSNC in an open manner would not be expected in a free market where a regulator keeps its distance from individuals in the market; and there are health policy issues such as continuity of service and patient access that dictate certain decisions, e.g. concession prices and PhAS.
- 6 In addition, the market is arguably not a normal market: pharmacy is in effect buying and supplying on behalf of the Government as part of the wider NHS; and the market is not competitive in every regard – for example, control of entry.
- 7 Furthermore, the NHS Act 2006 already provides some of the framework for Drug Tariff determinations: Section 164 provides supplementary information on determinations and includes:

(9)Any determination may be made only after taking into account all the matters which are considered to be relevant by the determining authority.

(10)Such matters may include in particular—

- (a) the amount or estimated amount of expenses (taking into account any discounts) incurred in the past or likely to be incurred in the future (whether or not by persons to whose remuneration the determination will relate) in connection with the provision of pharmaceutical services or of any category of pharmaceutical services,*
- (b) the amount or estimated amount of any remuneration paid or likely to be paid to persons providing such services,*
- (c) the amount or estimated amount of any other payments or repayments or other benefits received or likely to be received by any such persons,*
- (d) the extent to which it is desirable to encourage the provision, either generally or in particular places, of pharmaceutical services or the category of pharmaceutical services to which the determination will relate,*
- (e) the desirability of promoting pharmaceutical services which are—*
- (i) economic and efficient, and*
- (ii) of an appropriate standard.*

...