

PSNC Health Policy and Regulations Subcommittee Agenda
for the meeting to be held on Tuesday 9th May 2017
at Melia White House, Albany Street, Regent's Park, London, NW1 3UP
commencing at 13.45 in the Regent room

Members: Ian Cubbin (Chair), David Evans, Prakash Patel, Janice Perkins, Stephen Thomas.

Apologies for absence

At the time of setting the agenda, no apologies for absence have been received.

Minutes of previous meeting and matters arising

The minutes of the meeting on 14th March 2017 are set out in [Appendix HPR 01/05/17 \(pages 8-10\)](#).

Agenda and Subcommittee Work

Below is the progress and actions required against the subcommittee's work plan for the year. The Subcommittee is asked to consider the reports; to address any actions required; and to comment on the proposed next steps.

All ongoing matters not on the main agenda (and items closed at the last meeting) are set out in [Appendix HPR 02/05/17 \(pages 11-13\)](#).

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| 1 | Considering and where necessary, proactively seeking, potential changes in the regulatory framework that could support contractors and robustly responding to any Government proposals, including on remote dispensing and supervision |
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Report: ETP claims – Switching

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Report: Pharmacy Access Scheme – PhAS

The subcommittee has considered this matter before, most recently in March 2017.

The issues relate to incorrect PhAS calculations, the predicament of a number of LPS pharmacies and clarity on the review appeal provision added into the Drug Tariff in early 2017.

On 29 March 2017, representatives of PSNC met the DoH, during which time it was confirmed and agreed that there are significant issues with the calculations for PhAS payments. Discussions are ongoing and an oral report will be given to the subcommittee on 9 May.

A meeting is being arranged to discuss the predicament of certain LPS contractors and to clarify the appeal provision for reviews:

- LPS pharmacies returning to the pharmaceutical list are not eligible for PhAS payments, because they were not on the pharmaceutical list on 1 September 2016; and, applications for review are not available to them due to the terms of permitted reviews and because the closing date (28 February 2017) for most applications has passed.
- The DH has included a review appeals procedure in the Drug Tariff (page 734), but the detail of the procedure is not clear.

(As regards the recent announcement that there will be no further review decisions until after the election due to purdah, the Director of Operations and Support has been seeking clarification from NHS England, because purdah should not affect routine decision-making, only policy decisions.)

Subcommittee Action:

- No actions at this stage.

Next Steps:

- Ensure that PhAS calculations and payments are made in accordance with the Drug Tariff provisions.
- Ensure LPS pharmacies returning to the pharmaceutical list are entitled to a review for PhAS payments and those payments are appropriately assessed.
- Clarify the review appeal provision.

Report: Review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

The subcommittee has not considered this matter before.

The DoH has announced a review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 in accordance with regulation 121 of those regulations, which states:

Review of these Regulations

(1) The Secretary of State must, in accordance with paragraphs (2) to (4)—

- (a) carry out reviews of these Regulations;*
- (b) set out the conclusions of each review in a report; and*
- (c) publish each report.*

(2) Each report must in particular—

- (a) set out the objectives intended to be achieved by these Regulations;*
- (b) assess the extent to which those objectives have been achieved;*
- (c) assess whether those objectives remain appropriate; and*
- (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.*

(3) The first report under this regulation must be published before the end of 31st August 2017.

(4) Each subsequent report must be published before the end of the period of five years beginning on the day on which the previous report was published.

(Section 121 was amended by *The National Health Service (Pharmaceutical and Local Pharmaceutical Services)(Amendment) Regulations 2016*).

The review was due to be launched on 28 April 2017, but has been postponed due to the forthcoming general election and the purdah rules that apply as a result. Purdah is a convention, largely based on the civil service code. According to Sir Jeremy Heywood, Cabinet Secretary and Head of the Civil service, *'the key principle to keep in mind is that the civil service should do everything possible to avoid any activity that could call their political impartiality into question and to ensure that public resources are not used for party-political purposes.'*

Subcommittee Action:

- No actions at this stage.

Next Steps:

- Await the review process

Report: General Pharmaceutical Council consultation on revalidation

The GPhC is consulting on proposals to revise the standards on revalidation. The GPH summarises the proposals as follows:

Each year, pharmacy professionals must:

- make *declarations that they continue to meet our standards and remain fit to practice;*
- undertake, record and submit four CPD activities;
- undertake, record and submit a peer discussion; and,
- undertake, record and submit a reflective account against one of our standards for pharmacy professionals.

The GPhC also intends to ask for CPD records to be submitted every year at the same time that pharmacy professionals make their declarations for renewal of registration, and improve the review of submitted records.

The consultation document is available at:

https://www.pharmacyregulation.org/sites/default/files/consultation_on_revalidation_for_pharmacy_professionals_april_2017.pdf

The consultation document provides evidence based arguments for the proposed changes, which reduce and simplify the requirements for CPD; introduce peer discussion and a reflective account; simplify the overarching standards; and, concentrate on the purpose of the process – on its outcomes.

The February 2007 report, *Trust, Assurance and Safety – the regulation of health Professionals* - has dictated many of the regulatory changes in the last 10 or so years, including the introduction of revalidation (as well as the establishment of the GPhC). What the GPhC proposes is a continuation of the revalidation systems envisaged at that time and was summarised (paragraph 2.39, page 41) as:

*'...The [CPD] measures are framed in a way that is proportionate to the risk inherent in each professional group and designed to assure patient safety in relation to that risk. The Department believes that revalidation should be professionally led and proportionate and will work with the regulators for each profession to ensure that this is the case. It will be a complex undertaking to create workable and appropriate detailed arrangements for each profession involved and it will be important to **develop and adapt these proposals to ensure effective implementation...**' (my emphasis)*

This report is at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228847/7013.pdf

Subcommittee Action:

- It is suggested that PSNC should support the proposals.

Next Steps:

- Respond to the consultation before the closing date of 17 July 2017.

2 Ensuring administration of the regulations is undertaken properly and effectively, advising and supporting LPCs and contractors where necessary

Report: General Data Protection Regulation (GDPR)

The subcommittee has considered this matter before, in March 2017.

In response to a request, NHS England indicated that a series of guidance on the GDPR would be published soon via the Information Governance Alliance <https://digital.nhs.uk/information-governance-alliance>. This will be for the wider Health and Social care sector to use. This website indicates the guidance will be published by the end of April 2017 (now passed) and will include the following subject matters:

1. *CEO briefing 1: the GDPR and Accountability for Data Protection*
2. *Data protection accountability and governance*
3. *Privacy by design and default*
4. *Implications of the GDPR for Health and Social Care Research*
5. *Health and Social Care Research: legal basis and safeguards*
6. *Transparency, consent and subjects rights*
7. *Consent*
8. *Pseudonymisation [a way of processing a person's data without revealing their identity]*
9. *Personal data breaches and notification*
10. *Profiling and risk stratification*
11. *GDPR overview*
12. *What's new and what changes*

Subcommittee Action:

- No actions at this stage.

Next Steps:

- Await publication of the guidance.
- Provide guidance to contractors.

Report: Primary Care Support England (PCSE)

The subcommittee has considered this matter before, most recently in March 2017.

Stakeholder meetings

As regards the stakeholder meetings, recently, the Director of Operations and Support has attended the meetings and expressed concern that often Capita report a rosy picture of services involving market entry and pharmacy payments, while reports to PSNC suggest problems continue to exist. The minutes for the March 2017 stakeholder meeting record that:

'GH raised concerns that PSNC continues to receive reports of problems with market entry processing, and more recently with pre-registration payments, but that recognition of these problems is not reflected in Capita's reports. ' (March 2017)

Compensation

After PSNC requests for compensation for contractors, NHS England has set up a claims system for contractors who have been detrimentally affected by Capita's running of PCSE. PSNC announced this on 7 April 2017: <https://psnc.org.uk/our-news/capita-pcse-services-update-pharmacy-compensation-claims/> Contractors are encouraged to provide as much detail as possible, as NHS England will need to see evidence of loss or detrimental impact to the pharmacy and copy any claim to PSNC. An oral report on the types of claims to date will be given at the meeting.

NHS England has said that enquiries sent to the email address will be logged and acknowledged. Claims will be appropriately reviewed (by local teams if necessary), seeking further information as necessary. NHS England may then reject the claim or offer an appropriate goodwill payment. PSNC will continue to monitor the situation, providing more information to contractors should it become available.

Online portal for market entry applications

Capita is developing an online portal to handle the majority of market entry applications. On 30 April 2017, representatives from Capita (subcontractor Hunter Macdonald) and NHS England presented an outline of the proposed system. Mr Lutener, former Director of Regulation, and Mr Levitan, Chief Executive of Middlesex Pharmaceutical Group, kindly attended, to provide advice and comments. Broadly, the comments emphasised the need for:

- Good data for notifications and NHS consideration of which contractor to notify.
- Provision for anomalies in the process as they arise and the human input necessary to resolve them.
- Recognition of the complexity of the regulations, for example, decisions on postponement prior to notification.
- The significance of decisions to contractors.
- The provision of IT support (and associated finance) after the pilot for corrections to the portal.

At the main stakeholder meeting for the PCSE transformation process, the Director of Operations and Support raised the following concern and received the following assurance:

'Regarding market entry transformation, GH raised concerns about introducing the new solution on a problematic base. A web-based system has the potential to improve the market entry system, but implementation should not be at the cost and time of contractors. RT [Ryan Tabberner, PCSE] gave assurances that building on a stable base was a concern for Capita also, and the solution would only be introduced when it was appropriate to do so and would realise benefits.'

Subcommittee Action:

- No actions at this stage.

Next Steps:

- Continue to attend the monthly stakeholder meetings.
- To track the claims submitted to NHS England.
- To continue to offer comments on and monitor the development of the market entry online portal.

Report: Annual completion of the IG Toolkit and the actions of the NHS England West Midlands team.

The subcommittee has considered this matter before, most recently in March 2017.

NHS England stopped the process of withholding payments from affected contractors, but has declined to acknowledge it was at fault or provide any proper explanation for its actions. PSNC and the West Midlands LPCs maintain that NHS England breached the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

There are ongoing discussions and a meeting with NHS England is planned for 12 May 2017.

Subcommittee Action:

- No actions at this stage

Next Steps:

- LPCs to meet with NHS England on 12 May 2017; the Director of Operations and Support will attend.
- Escalate concerns within NHS England, if appropriate, to obtain a proper explanation from NHS England for its actions in 2016.

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Report on progress on matters previously discussed by the subcommittee (May 2017 Agenda)

Matters worked on between May 2016 to present			
Item	Most recent action	Current status	Date of last subcommittee meeting
Judicial Review	<p>Main Committee Agenda</p> <p>This item includes a previous item on planned committee closures.</p> <p>The judicial review hearing concluded on 24 March 2017 and the judgment is awaited</p>	Open	03/17
General Data Protection Regulations (GDPR)	<p>Agenda item</p> <p>See NHS England guidance awaited at https://digital.nhs.uk/information-governance-alliance.</p>	Open	03/17
Discretionary payments and “switching” etc.	Agenda item.	Open	03/17
Planned protection for patient access – PhAS	Agenda item.	Open	03/17
Visitor and Migrant cost recovery	<p>See Government update dated 6 February 2017 at https://www.gov.uk/government/collections/nhs-visitor-and-migrant-cost-recovery-programme</p>	Open	03/17
Market entry	Statutory consolidations – PSNC guidance awaited	Open	03/17
Equality Act and its applicability to the provision of MDS trays	The existing Jan 2016 guidance is to be revised.	Open	03/17

Accessible Information Standard	NHS England conducted a post-implementation review of the Standard and is analysing the responses https://www.england.nhs.uk/ourwork/accessibleinfo/	Open	03/17
Direction of Prescriptions	How to address the issues will be considered in 2017/18	Open	10/16
ToS for DSPs	On 20 October 2016, as part of the Government funding imposition, DH confirmed that it is their intention to explore new terms of service for distance-selling pharmacies in recognition of their different service offering. This will be the subject of further consultation with PSNC. See paragraph 3.46 of the imposed decision (final package) at: https://www.gov.uk/government/publications/community-pharmacy-reforms	Open	10/16
Hub & spoke	The DH consultation has closed – no further action yet and DH website last updated on 9 June 2016. See https://www.gov.uk/government/consultations/pharmacy-dispensing-models-and-displaying-prices-on-medicines	Open	09/16
Rebalancing	In 2016, the Director of Operations & Support has followed up requests to DH to be part of the working group on supervision, but without success. For relevant information and attendees, see: https://www.gov.uk/government/groups/pharmacy-regulation-programme-board Pharmacy Voice was a member of the its supervision working group and there is a note of the terms of reference at: https://app.box.com/s/75cii16v58e80r2g1p9k/1/6016425233/48900987953/1	Open	07/16
FMD	Delegated Acts issued. Department of Health currently holding meetings with stakeholders regarding implementation; discussion halted due to purdah convention. Discussion with SDS. For general information, see http://psnc.org.uk/contract-it/pharmacy-regulation/falsified-medicines-directive/	Open	07/16

Conflicts of interest	NHS England's updated guidance (February 2017) on the management of conflicts of interests. See guidance at (page 3 for pharmacy) https://www.england.nhs.uk/ourwork/coi/	Closed	03/17
PNA's	PNA questionnaire for use by LPCs has been revised and made available	Closed	03/17
GPhC consultation on religion, personal values and beliefs in pharmacy	GPhC has said that it has 'approved the wording of the new proposed standard' and that it will be asking its Council 'to agree the final version of the guidance at its meeting in June'. See https://www.pharmacyregulation.org/news/gphc-council-agrees-new-wording-standard-1-new-standards-pharmacy-professionals-following	Closed	03/17
Health Services Medical Supplies Bill – now Act having received Royal assent on 27 April 2017	The Act makes ' <i>provision in connection with controlling the cost of health service medicines and other medical supplies; to make provision in connection with the provision of pricing and other information by those manufacturing, distributing or supplying those medicines and supplies, and other related products, and the disclosure of that information; and for connected purposes</i> ' (introductory text). It also includes a late amendment on specials was included in the Act, see: http://www.legislation.gov.uk/ukpga/2017/23/pdfs/ukpga_20170023_en.pdf	Closed	03/17

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