

# PSNC Health Policy and Regulation Subcommittee Minutes

Of the meeting held on Tuesday 12th July 2016

At The Athenaeum, Church Alley, Liverpool, L1 3DD

Commencing at 2.30pm

**Present:** Ian Cubbin (Chair), David Evans, Margaret MacRury, Prakash Patel, Janice Perkins

**Together with:** Gordon Hockey, William Goh.

## Apologies for absence

There was none.

## Minutes of previous meeting and matters arising

The minutes of the meeting held on 12<sup>th</sup> January 2016 were approved.

## Report of ongoing work

The report was noted.

## Agenda and subcommittee work

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| 1 | Proactively seek changes in the regulatory framework that support contractors and will robustly respond to proposals from the Department of Health and NHS England |
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### a. Pharmacy numbers – planned reduction

The information was noted and it was confirmed that the committee would have to approve any judicial review by or on behalf of PSNC.

### b. Market entry

It was noted that the proposed regulatory changes will facilitate consolidation of pharmacies - to reduce clusters – and that there will be at least a triple lock protection against other pharmacies opening up in response to a consolidation of:

1. HWB must comment on an application;
2. NHS England may only grant an application if no gap is created; and,
3. An unforeseen benefits application subsequently based on the consolidation must fail.

Also sought was a requirement for the HWB to issue a supplementary statement (which is public) that confirms no gap was created following the consolidation.

The subcommittee noted that the protection of (3) only lasts until the next PNA and this is not later than 2018. The subcommittee considered that longer protection until approximately 2020 was appropriate and recommended:

## PSNC seek to extend the reissue of the PNA to every 5 years

### c. Planned protection for patient access - PhAS

It was noted that the item is currently being considered in the plenary committee sessions, but the detail of the scheme is not yet known.

Until the structure of the scheme is known, the subcommittee's work is in abeyance.

#### **d. Hub and spoke / centralised dispensing**

The PSNC response to the DH consultation was noted as well as the Minister's announcement that DH would not be introducing the proposed legislation in October 2016.

It was commented that on the subcommittee and committee there were mixed views about the issues; also that the DH consultation sought to introduce hub and spoke dispensing between clinical settings.

The Director of Operations and Support indicated that he and the CEO would be attending a DH stakeholders and representative bodies meeting on 6 September 2016.

#### **e. Rural working group**

The minutes of the group's meeting on 29 February 2016 were noted.

#### **f. Accessible information standard**

The information was noted and it was agreed that implementation of the standard should be reviewed after NHS England's anticipated September review.

It was commented that the GPhC already assesses or partially assesses accessibility of information as part of its inspections of pharmacies.

#### **g. Rebalancing (Supervision)**

It was noted that the Director of Operations and Support had asked the DH if he could be a member of the group considering supervision; a response is awaited.

It was commented that currently, the group is reviewing the roles of the superintendent pharmacist and responsible pharmacist prior to work on supervision.

2 PSNC will address operational issues affecting pharmacy practice, working to secure the best outcomes for contractors.

#### **a. Falsified Medicines Directive**

##### **Delegated Regulation UK MVO consultation:**

The Falsified Medicines Directive seeks to provide a European framework to record and monitor medicines in the supply chain, to seek to minimize the introduction of false or counterfeit medicines.

It was noted that representatives from five stakeholder groups, led by manufacturers, are consulting about the structure, governance and role of the UK Medicines Verification Organisation, the UK repository of relevant data, which connects to a European hub. The group includes the CCA and NPA as representatives of dispensing entities.

When the UK MVO is established there will be five voting directors, one from each of the five stakeholder groups. Those organisations with voting directors must pay towards the cost of the establishment and governance of the organisation. It was reported that the NPA and CCA intend to share the voting director for dispensing entities; alternating it every 12 months, and that Raj Patel will be the first director.

The subcommittee considered that PSNC and the other pharmacy organisations representing NHS contractors should be represented on the UK MVO; noting that the Delegated Regulation provided that dispensing entities could participate in the MVO on a voluntary basis, at no cost. The subcommittee recommended that the response include:

[PSNC wishes to participate in the UK MVO, without contributing to its costs.](#)

Also, post-Brexit, the subcommittee considered while it was still likely the Government would implement the Delegated Regulation in some form, PSNC should nevertheless seek to reduce the scope and cost of implementation for contractors by raising the issue; arguing that its introduction post Brexit was voluntary for the Government and not a regulatory burden for contractors. The subcommittee recommended that the response include:

The impact, if any, of the UK Brexit vote to leave the EU should be considered, because the Government might wish to reduce the scope and, therefore, cost of its implementation.

Finally, it was agreed that the PSNC response should point out that the UK Medicines Verification Organisation (MVO) has a role to play monitoring and investigating alerts, so that community pharmacy contractors can pass these to the UK MVO to resolve.

#### **b. Direction of prescriptions**

The information was noted.

#### **c. Primary Care Support England (PCSE)**

The subcommittee noted the information and the ongoing commitment by PSNC staff to attend the stakeholder meetings with PCSE/Capita.

Subcommittee members indicated that following the problems with controlled stationery they were starting to see problems with market entry – e.g. a lack of notification. This view was supported with calls and complaints about Capita that have been received by the office. The Director of Operations and Support indicated that the concerns had been raised at the stakeholder meetings and also in a separate meeting with Capita.

There was a general view amongst subcommittee members that the support provided by Capita was so poor that it impacted on the time pharmacists had to support and care for patients and, therefore, impacted on patient care; and impacted on the smooth running of the pharmacy business, and was unacceptable.

The subcommittee's view was that the concerns should be taken up with NHS England and it recommended to the committee that:

PSNC seek a meeting with NHS England, and potentially other stakeholders, to discuss the problems with service delivery.

[At the committee, the recommendation was revised to PSNC writing a letter to NHS England setting out the problems with service delivery.]

#### **d. Community Pharmacy Assurance Framework (CPAF)**

The subcommittee noted the information and noted the good response from contractors.

It was agreed that the office would provide information to contractors on the CPAF timetable indicating that with the CPAF screening questionnaire process completed in June, relevant pharmacies would be invited to complete the full CPAF in September / October and then any visits should be conducted after this time, if required.

#### **e. Visitor and migrant NHS cost recovery programme delivery**

The subcommittee noted the information.

If was commented that even if the work is funded, it is not an appropriate work for community pharmacy.

#### **f. Special containers**

The subcommittee noted the information.

**g. Managed repeats**

The subcommittee noted the information.

**h. Switching**

The subcommittee noted the information on the general issue relating to switching of EPS prescriptions submitted to the BSA; and the specific claim/case which is being supported by PSNC.

**Any Other Business**

The General Data Protection Regulation (GDPR) was adopted in December 2015. The GDPR will be directly applicable in all Member States without the need for implementing national legislation. It will come into effect in May 2018.

New European regulations on data security were introduced in December 2015.

The office was asked the office to issue appropriate guidance on these provisions to contractors.