

PSNC Health Policy and Regulations Subcommittee Report

for the PSNC March 2016 meeting

at Bristol Marriott Royal, College Green, Bristol, BS1 5TA

Members: Ian Cubbin (Chair), David Evans, Margaret MacRury, Prakash Patel, Janice Perkins.

Report and Subcommittee Work

This is an update for the Health Policy and Regulations subcommittee. In light of 17 December 2015 DH / NHS England letter PSNC will devote all of the March 2016 meeting to considering that letter, all the intervening developments, and to set a framework for ongoing negotiation. Therefore the HP&R subcommittee will not meet separately and this report is to bring the subcommittee up to date with relevant matters.

Report of progress on matters previously discussed by the subcommittee

To assist the subcommittee in tracking progress, all matters that have been considered by the subcommittee are set out in a progress report in the **Appendix**

The progress report provides an update on matters progressed between October 2014 to January 2016 with the last action taken and its status. For matters that have a simple update after the last substantive subcommittee meeting, the update is included in square brackets. Items are removed from the report 12 months after closure to keep the size of the table reasonable.

Standard agenda items

- 1 Secure changes to the regulatory framework governing provision of pharmaceutical services that support and protect the interests of contractors

Report: Rural Working Group

Details of nominations for new members was given as well as an update on the impact of the Government's proposals on community pharmacies in rural locations, covering such topics as the Pharmacy Access Scheme, market entry, and hub and spoke.

Report: Accessible Information Standard

Details of PSNC's work in this area were highlighted.

Report: EU General Data Protection Regulation (GDPR)

On 15 December 2015 the EU Commission published a [press release](#) indicating final agreement between the three EU institutions following trilogue negotiations on the text of the GDPR. In summary, agreement has been reached on new data protection rules, establishing a modern and harmonised data protection framework across the EU. Once the Regulation receives formal adoption from the European Parliament and Council (expected between January to April 2016), the official texts will be published in the Official Journal of the European Union in all official languages. The new rules will become applicable two years thereafter.

The UK Information Commissioner's Office (ICO) considers that 2017 is optimistic with deputy commissioner David Smith stating in his [blogpost dated 7 September 2015](#): 'On the most optimistic forecasts, the two-year run-in period is unlikely to start much before June 2016, with the Regulation in force in June 2018, though end of 2018 might be a more realistic prospect'.

Report: FMD

Raj Patel and Gareth Jones provided an update briefing to PSNC/CPW/CPS and CPNI on 26 January 2016.

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It was reported that the delegated acts, which require authentication at the time of handing to the patient had not been expected by the MHRA. It had been thought that it would be drafted to allow some flexibility.

We were also informed that the delegated acts allow the government to exempt hospitals and dispensing doctors from the authentication measures at the time of supply.

A UK FMD group, consisting of CCA, AIMp and NPA representatives was in discussions with system suppliers about changes that will be needed. The NPA and CCA are also represented on the UKMVO which will shortly decide the appointment of the organisation to establish the UK data repository.

The delegated acts are expected to become law during February, and this is expected to set the implementation deadline of 1 March 2019.

The four home country negotiating bodies will be discussing the approach that should be taken to negotiations with the NHS.

Report of progress on matters previously discussed by the subcommittee

Matters worked on between October 2014 to present (starting with most recent open workstream items and descending to closed workstream items)			
Item/description of workstream	Most recent action/s	Current status	Date of last subcommittee meeting
Hub & spoke	Director of Regulation & Support to attend working. Hub and spoke will be considered as part of rebalancing.	Open	01/16
Accessible Information Standard	Office to continue working with the primary care professions and encouraging NHS England to make the accessible information standard workable.	Open	01/16
Rebalancing	Director of Regulation & Support requested DH to be part of the working group on supervision and is awaiting a response.	Open	01/16
Charges regulations matters including "switching", discretionary payments etc.	"On hold" pending community funding consultation outcome. The office continues to press DH for action. Awaiting formal response from DH with proposed Drug Tariff amendments and wording proposals. Awaiting confirmation of policy on discretionary payments from NHS England.	Open	01/16
FMD	Delegated Acts issued. System suppliers to look at options. PSNC to keep watching brief on developments. PSNC hosting a meeting in January 2016 with other UK home countries at which NPA will provide an update / briefing	Open	01/16
Rural Working Group (RWG) ToR need amendment and members appointed	Subcommittee approved amendments to ToR and canvas nominations for membership of RWG with Chairman and Director of Regulation and Support agreeing the nominations.	Open	01/16

National Provider company	PSNC agreed to support a national provider company with £25,000 to cover the remaining part of the year, subject to the NPA matching this funding pledge. It is envisaged that the national provider company will proceed to incorporation in due course [instructions to lawyers to prepare draft Articles issued].	Open	01/16
Pregabalin	No change to NHS guidance - refer back to prescriber if Lyrica intended. An appeal against the High Court decision is pending. Noted that Wales LHB have issued contrary guidance, PSNC to contact CPW. [CPW subsequently confirmed no problems at present].	Open	10/15
Co-Commissioning	Informal discussions so far. Legislation may need to be amended, and the co-commissioning will be “complementary and supplementary to the core contract”.	Open	10/15
APPG	Continue to work with Pharmacy Voice and the RPS to engage with politicians to promote the services that pharmacies can offer and to support the APPG.	Open	10/15
Application timescales	On 1st September 2015, Capita took over responsibility for primary care support services PSNC as part of the PCS stakeholder forum have raised examples of where NHS England have failed to abide by the timescales set down in the regulations for determining applications. [Director of Regulation and Support discussing with Capita].	Open	10/15
Application consultation: LPCs and interested parties NHS England not consulting properly on new applications	On 1st September 2015, Capita took over responsibility for primary care support services PSNC as part of the PCS stakeholder forum have raised examples of where NHS England has not consulted adequately. [Director of Regulation and Support discussing with Capita].	Open	10/15
Prices on labels	No formal communication on this policy from the Department.	Open	07/15
CG – IG -Business continuity plan	[PSNC to draft template].	Open	07/15

Dispensary Waste confusion if Rx waste can be included	Waste procurement exercise ongoing.	Open	05/15
Return of denatured CDs	Subcommittee discussed whether this was a significant issue - believed that it was isolated and best dealt with locally. A request for further particulars made in October 2015.	Closed	10/15
Inducements	DH taking no further action – suggested that PSNC might raise during negotiations with NHS England.	Closed	10/15
7-day access	Pharmacy may be encouraged into 7 day access like GPs noted.	Closed	10/15
Contract monitoring/CPAF Including reports of inappropriate action	CPAF lite a success. [Full CPAF for those selected for possible visit being prepared for January].	Closed	10/15
LA Commissioning Failure of LA to consult LPC.	Noted [National primary care representative bodies to work with LRCs – NHS England on memorandum of agreement setting out the roles and functions – will recommend LRCs as consultees.	Closed	10/15
Messages on RHS Rx	Reported and noted that HSCIC will update guidance to GPs on the appropriate use of RHS.	Closed	10/15
NHS Standard Contract	The office submitted response to the proposals for the NHS Standard Contract 2016/17. [A copy of the response is available on request from Director of Regulation and Support]. The draft shorter NHS Standard Contract has been reviewed and comments provided to NHS England prior to the formal consultation by the end of the year. [A copy is available on request from the Director of Regulation and Support].	Closed	10/15
Charge for carrier Bags	Legislation introduced 5 pence charge for single use plastic carrier bag which is now effective in England. Noted.	Closed	10/15
Boxing day 2015 Query about status of 26/12	Publicity give to contractors, as NHS England taking a hard line.	Closed	07/15

Pharmacy Closures 2 nearby pharmacies. If close one creates a gap. Discussed with NHSE and DH	Some guidance already provided by DH to HWB. PSNC to write LPC briefing. [covered in PSNC market entry events. Article written for LPCs (12/15)].	Closed	07/15
FtP - Superintendent named on applications	For NHS England to decide whether there needs to be change.	Closed	07/15
GPhC fees consult – response to consultation	PSNC response submitted and noted that GPhC confirmed that the proposed fees increase would take place.	Closed	07/15
Supply of CDs in police custody – guidance in development	Guidance published and noted.	Closed	07/15
NHS Fraud - exemption checking Reference to DH announcement	No developments.	Closed	07/15
EPS Schedule 2 & 3 controlled drugs - regs to be amended	Changes came into force 1st July 2015. Now awaiting action by system suppliers.	Closed	07/15
Post election lobbying	Update on conferences to date PSNC's fringe events at the Labour and Conservative Party Conferences were well attended and good discussions were had with ministers, councillors and other health professions (the CEO will report on these events in the PSNC plenary session).	Closed	07/15
GPhC consult - Investigating Comm.	Not PSNC's role and remit.	Closed	07/15
Psychoactive substance bill	Reported and noted.	Closed	07/15
GPhC Inspections Report published. No further action	Report published by the GPhC setting out a provisional timetable (dependent on parliamentary approval) for full implementation of the inspection model, with publication of inspection reports. No further action for the subcommittee.	Closed	05/15
HSJ supplement	It was reported and noted that there will be 3-4,000 spare copies many of which available to LPCs for their own local discussions.	Closed	05/15

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PNA Enh services	PNAs have been published. It was noted in the agenda that the current PNA remains in place until the HWB PNA is published.	Closed	05/15
Homecare	Reported to the subcommittee that the homecare market is flaky and the research undertaken as part of the MBA could help identify opportunities for community pharmacy to integrate with homecare. No subcommittee action required.	Closed	05/15
Francis review	The report was considered and no further action needed.	Closed	05/15