

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee

Minutes For the meeting held

At the De Vere Grand Connaught Rooms, 61-65 Great Queen St, London

On Wednesday 24 November 2021

Members of LRA present: Ian Cubbin (Chair), Marc Donovan, Ifti Khan, Stephen Thomas (Vice-Chair).

In attendance: David Broome, Mark Burden, Peter Cattee, Sam Fisher, Mark Griffiths, Jas Heer, Tricia Kennerley, Gordon Hockey, Clare Kerr, Rhys Martin, Lucy Morton-Channon, Roger Nichols, Fin McCaul, Has Modi, Bharat Patel, Indrajit Patel, Jay Patel, Adrian Price, Sian Retallick, Layla Rahman, Anil Sharma, Faisal Tuddy 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

3. There were no new conflicts or declarations of interest.

Minutes of the last meeting

4. The minutes of the subcommittee meeting held on 19 May 2021 were approved.

Actions and Matters Arising

5. There were no matters arising.

Update on negotiations, PSNC papers - DSPs, non-NHS pharmacy premises and prescription direction

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Note: includes information confidential to PSNC members

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Mandatory COVID-19 vaccinations

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DHSC consultation on Original Pack Dispensing (OPD) - confidential until the response is complete

20. The agenda paper was noted by the subcommittee and that earlier in the day, FunCon had given broad approval to exploring with DHSC the Scottish model of OPD.

21. The proposed points in response to the consultation were agreed in broad terms subject to the following comments and observations:

- a) As noted in the paper, the proposed changes to the HMRs were unlikely to be enough to support the changes within the Scottish model – the 10% is not enough in all circumstances;
- b) OPD should not be available for controlled drugs of schedule 2, 3 and 4;
- c) Our response and view to the consultation represents that of the sector nationally – we must seek assurances that it will be weighted accordingly against other responses;

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- d) Looking forward to NHS OPD, what is permitted should not be overly complicated.

22. Action: To respond to the DHSC along the lines set out in the agenda paper and as discussed.

Reports

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Advance paper: PSNC Pharmaceutical Needs Assessment guidance (LRA and LCS)

24. The advance paper and earlier LRA decision were noted, and that the LPC guidance has been published.

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DHSC consultation on expanding access to naloxone – PSNC response

30. The consultation response was noted.

CPAF update

31. The office reported that recent information from NHSE&I was that: of the 638 pharmacies that had been asked to undertake the full CPAF (including those who had not completed the screening questions), 145 had completed the form, 217 had accessed it and 276 had not started it. There was discussion on compliance with the requirement

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and the office reported its initial conversation with NHSE&I that an individual approach should be taken with contractors, due to the current acute workforce issues: that a contractor working excessive hours would be unlikely to find the time to complete it.

32. There was concern from the subcommittee and other committee members present about CPAF continuing and the general view was that the process including visits should cease due to the acute workforce issues.
33. It was noted that this and other regulatory requirements would be picked up at committee meeting tomorrow.

AOB [added after the meeting to report]

34. [It was noted that a response had been made to the current MHRA consultation on the future regulation of medical devices in the UK, indicating that community pharmacies are suppliers of medical devices (referred to as one of a number of distributors in the consultation based on EU legislation) and while ensuring patient safety, there is a need to consider carefully and minimise additional requirements on community pharmacy, where the requirements could be more appropriately directed at others in the supply chain or the aims could be achieved using existing information in the supply chain (e.g. with wholesalers) or the NHS (e.g. in medical records).]
35. [It was noted that the CPPQ Approved Particulars suggested by PSNC had been approved by NHSE&I.]

No.	Action (confidential)	Responsible
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Action 3	To respond to the DHSC consultation on OPD along the lines set out in the agenda paper and as discussed at the meeting – broadly accepting suitable changes to the Human Medicines Regulations.	GH