

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee Agenda

For the meeting to be held on Wednesday 27 November 2019

At 14 Hosier Lane, London EC1A 9LQ

Members: Ian Cubbin (Chair), Marc Donovan, Jas Heer, Janice Perkins, Stephen Thomas.

1. Welcome from Chair
2. Apologies for absence
3. Conflicts or declaration of interest
4. Minutes of the last meeting in May 2019 ([Appendix 01/11/2019](#)).
5. Matters Arising

Action

6. Consolidations and prescription direction (confidential) ([Appendix 02/11/2019](#))
7. Dispensing/delivery models and hub and spoke dispensing between legal entities and DSPs – ongoing initial consideration (confidential) ([Appendix 03/11/2019](#))

Report

8. Brexit update ([Appendix 04/11/2019](#))
9. Technology forum (confidential) ([Appendix 05/11/2019](#))
10. Consultation on needs-based regulation in Wales (confidential) ([Appendix 06/11/2019](#))
11. Regulation of professionals including the pharmacy team ([Appendix 07/11/2019](#))
12. Government/NHS proposals for legislation – Supporting the NHS ([Appendix 08/11/2019](#))
13. Primary Care Support England update (confidential) ([Appendix 9/11/2019](#))
14. Any other business

Pharmaceutical Services Negotiating Committee

Legislation and Regulatory Affairs Subcommittee

Minutes of the Legislation and Regulatory Affairs Subcommittee meeting held on 4 September 2019.

Members: Ian Cubbin (Chair), Stephen Thomas (Vice Chair), Janice Perkins, Jas Heer, Marc Donovan.

In attendance: Gordon Hockey, Will Goh, Sam Fisher, Tricia Kennerley, Andrew Lane, Has Modi, Peter Cattee, David Broome, Bharat Patel.

Apologies: There were no apologies for absence.

Conflicts of Interest: There were no additional conflicts of interest declared.

Minutes: The minutes of the meeting on 22 May 2019 were approved with a minor grammatical amendment to 4.2 (c): 'directed' not 'direct'. There were no matters arising.

Item 1 – Hub and Spoke dispensing/delivery models – initial consideration - confidential

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Item 2 – Prescription direction - confidential

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Item 3 – Rural working group report and updated terms of reference– open

3.1 The report was noted, and the updated terms of reference were approved.

Matters of Report

Item 4 – Brexit update – the notes of two recent meetings of the Community Pharmacy Brexit Forum and a note relating to medicines with short expiry dates were attached - open

4.1 The reports were noted.

4.2. The function of the forum was raised, and it was reported that the forum:

- a) remained a focal point for DHSC and NHSE&I to communicate key messages to the community pharmacy sector;
- b) received updates on the broad level of preparation in the rest of the medicines supply chain;
- c) had assisted with discussions on serious shortage protocols;
- d) considered issues in relation to medicines and medical devices;
- e) considered issues in relation to contractor readiness for Brexit and considered the PSNC briefing for contractors;

- f) discussed contractor reporting of issues relating to Brexit – which will use business as usual systems;
- g) assisted the DHSC to find additional trusted sources to provide information on the supply chain;
- h) maintained the message to the sector not to stockpile medicines and medical devices beyond business as usual;
- i) liaised on communications messaging to ensure a consistent approach by the sector and one consistent with the Government; and,
- j) provided a forum for members to report relevant Brexit issues to DHSC and NHSE&I.

4.3. There was a brief discussion on Government preparations for the continuity of supply of medicines in the event of a no-deal Brexit and a variety of views were expressed. Gordon Hockey reported that Government plans remained robust and it was anticipated that similar to the last deadline, greater evidence of stockpiling by manufacturers and alternative arrangements would be made available to the DHSC's continuity of supply group to provide greater assurance.

Item 5 - Community Pharmacy Assurance Framework (CPAF) - open

5.1 The report was noted.

Item 6 – Primary Care Support England - open

6.1 The report was noted.

6.2. Will Goh confirmed that the current planned 'go live' date for the market entry portal is November this year. It was expressed that the thoroughness of the user acceptance testing scheduled for mid-September was less than desirable as testing is now restricted to PCSE's headquarters in Leeds rather than remotely which had been promised.

Any other business

The Chair indicated that this is Will Goh's last subcommittee meeting as he is moving on and he and the subcommittee thanked him for his support and work and wished him all the best in the future.

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Appendix 07/11/2019

Subject	Regulation of professions including the pharmacy team
Date of meeting	27 November 2019
Committee/Subcommittee	LRA
Status	Open
Overview	Report
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Background

1. This report is to note the DHSC response to the consultation 'Promoting professionalism, reforming regulation' published in July 2019.
2. DHSC has indicated it will prioritise three changes.
 - First, *modern and effective fitness to practice procedures* – which includes providing healthcare regulators with broadly consistent powers to handle fitness to practise cases and introducing means for them to resolve cases without a full hearing; potentially giving the PSA additional powers to review such cases.
 - Second, *better support for professionals* – which seems to be a consequence of the early resolution of cases freeing up time for regulators to support professionals; and
 - Third, *more responsive and accountable regulation* – which includes allowing regulators to quickly amend day-to-day practices (without the need for any legislation) and improving their governance, for example, by requiring an annual nation specific report to each legislature in which they operate. As is evident by these proposals, the development of regulation of health and social care professionals described in the rest of this chapter is still in progress.

Appendix 8/11/2019

Subject	Government/NHS proposals for legislation – Supporting the NHS
Date of meeting	27 November 2019
Committee/Subcommittee	LRA
Status	Open
Overview	Report
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Background

1. In the Queens Speech to Parliament the following legislation was proposed to support the NHS:
 - NHS Long Term Plan
 - Health Service Safety Investigations Bill
 - Medicines and Medical Devices Bill
 - Adult social care
 - Mental health reform
2. While these will not progress at this time – due to the dissolving of Parliament and the general election – they may be put forward at a later time.
3. Aspects of particular significance to community pharmacy include proposed reforms to the NHS and the Medicines and Medical Devices Bill.

NHS Long Term Plan

4. Earlier this year NHS England carried out a pre-consultation consultation called 'Implementing the NHS Long Term Plan – Proposals for possible changes to legislation'. This

has been followed with recommendations to Government and Parliament for an NHS Bill (see <https://www.longtermpian.nhs.uk/nhs-publishes-response-and-recommendations-on-long-term-plan-legislative-proposals/>)

5. The proposals include primary and secondary care and the implication are not clear at this stage, but key aspects of this for pharmacy include:

Medicine pricing

23. The CMA has powers to investigate alleged infringements of competition law and particular markets if it sees issues for consumers with reducing competition. The CMA has used these powers – for example in relation to the pricing of pharmaceuticals – to protect the public interest. We said we saw clear benefit in the CMA continuing this role.

Freeing up procurement rules by revoking currently applicable competition Act provisions

63. Our engagement document proposed:

regulations made under section 75 of the Health and Social Care Act 2012 should be revoked and the powers in primary legislation under which they are made should be repealed

NHS services are removed from the scope of the Public Contracts Regulations 2015 NHS commissioners are instead subject to a new “best value” duty, supported by statutory guidance and

the power to set standing rules in primary legislation is amended to require inclusion of patient choice rights

64. The drive for greater integration of care set out in the NHS Long Term Plan is a continuation of the direction of travel established by the NHS Five Year Forward View (2014).

65. However, this will be harder to achieve while the NHS is subject to the current procurement and tendering rules which in the view of providers and commissioners can frustrate attempts to integrate care at scale, disrupt the development of stable collaborations, and involve protracted processes with wasteful legal and administration costs.

66. The NHS is currently subject to two sets of procurement rules – the National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013 (PPCCR) made under section 75 of the Health and Social Care Act 2012, and the Public Contracts Regulations 2015 (PCR), a set of public procurement rules which transposed the EU Directive on Public Procurement into UK law. Under the latter, contracts for health care services over a certain amount (currently £615,278 over the lifetime of the contract) need to be advertised and the applicable procurement procedures must be followed.

86. Respondents were unclear what is meant by 'NHS providers' in the proposal, and whether we were deliberately limiting the new regime to arrangements made with statutory NHS

bodies (i.e. NHS trusts and foundation trusts). Some respondents favoured the idea that new NHS procurement regime could be a means of prioritising NHS statutory providers over independent sector providers. However, others were concerned that if the proposals excluded non- statutory providers the consequences may be that patients suffer a lack of choice; that the important role played by the voluntary sector, social enterprises, and mutual organisations could be systematically diminished; that GPs and primary care networks, and community pharmacies may be excluded; and that monopolistic behaviour against the public interest may emerge.

87. For clarity, we intend that this new regime covers all arrangements, not just arrangements with NHS statutory providers. Some respondents asked whether the new NHS procurement regime would also apply in the purchasing of goods. Our recommendation is that the new arrangements would apply only to the commissioning of healthcare services.

Recommendation 4: Regulations made under section 75 of the Health and Social Care Act 2012 should be revoked and the powers in primary legislation under which they are made should be repealed

Recommendation 5: The commissioning of NHS healthcare services is removed from the scope of the Public Contracts Regulations 2015

Recommendation 6: Introduce a new NHS procurement regime, supported by statutory guidance

NHS England delegating powers to CCGs

Recommendation 20: Give NHS England the ability to delegate its functions to groups of CCGs, in order to enable them to collaborate more effectively to arrange services for their combined populations

296. Existing powers in the 2006 Act enable joint commissioning or delegation of these NHS England functions to a single CCG; or through changes resulting from the Cities and Local Government Devolution Act 2016, to a CCG and local authorities or combined authority. Our proposals would future-proof the current legislation by enabling groups of health bodies to have this same flexibility to make arrangements for primary medical care, primary dental services, community and other prescribed secondary dental services, core pharmaceutical services, ophthalmic services, armed forces healthcare, and health and justice services alongside their other health services.

297. This flexibility would not be without safeguards. Specific proposals to delegate or jointly commission e.g. armed forces healthcare or health and justice services would need to demonstrate that they have a clear supporting rationale, as there are benefits in having a single national model to deal with these specific groups of patients. Whilst delegation could only happen on terms that NHS England and NHS Improvement considers appropriate, we plan to introduce specific safeguards in legislation (primary or secondary) – not least if we propose to enable pooling of budgets.

Recommendation 21: Enable NHS England to enter into formal joint commissioning arrangements with CCGs including providing the ability to pool budgets in relation to specialised commissioning

Comment

6. The main elements of the Medicines and Medical Devices Bill are stated by DHSC to be (See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/839370/Queen_s_Speech_Lobby_Pack_2019_.pdf#page=36):
 - Powers to remove unnecessary bureaucracy for the lowest risk clinical trials, encouraging the rapid introduction of new medicines.
 - Ensuring patient safety by implementing a scheme to combat counterfeit medicines entering supply chains and a registration scheme for online sellers.
 - Enabling Government to increase the range of professions able to prescribe low-risk medicines to make the most effective use of the NHS workforce, as well as developing more innovative ways of dispensing medicines, where recommended by scientific experts.
 - Extending our global lead in personalised medicine and Artificial Intelligence in health. Our regulators, the Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate, will be able to develop innovative regulation to enable early access to cutting edge technologies and break new ground in complex clinical trials
7. It was also proposed that the Act would deal with FMD related issues, a registration scheme for online sellers of medicines, as well as increased range of professions prescribing low risk medicines.
8. Confidential - It is also understood from DHSC that hub and spoke proposals were within the package.

Comment

9. PSNC may need to seek specialist advice on the proposals concerning competition related issues if a formal consultation proceeds in due course
10. As an additional comment, the rebalancing Boards legislative proposals – considered by the subcommittee last year – and then subsequently the term ‘at and from’ to be included throughout the Medicines Act in relation to the business of a retail pharmacy business - in February this year, do not seem to have progressed, at least to date.

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