

PSNC Legislation and Regulatory Affairs (LRA) Subcommittee

Minutes For the virtual meeting held on

Monday 7 September 2020

Members of LRA present: Ian Cubbin (Chair), Marc Donovan, Janice Perkins, Stephen Thomas.

In attendance: David Broome, Mark Burden, Alastair Buxton, Peter Cattee, Simon Dukes, Jas Heer, Gordon Hockey, Tricia Kennerley, Has Modi, Garry Myers (for the last agenda item), Prakash Patel, Sian Retallick, Layla Rahman 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

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Minutes of the last meeting

3. The minutes of the subcommittee meeting held on 29 July 2020 were approved.

Actions and Matters Arising

4. There were no matters arising.

NHS amendment Regulations

5. Gordon Hockey introduced the paper and in turn each of the four aspects for decision were considered. All were agreed with one caveat stated for the second aspect.
6. The first, is the **Pandemic Treatment Protocol (PTP)**, which introduces an additional aspect to the essential dispensing service similar to the provision for Serious Shortage Protocols – activated when required. If a contractor receives an electronic message through a secure service that orders the supply of drugs in accordance with a PTP and a person is entitled to such supply (it is envisaged that a patient would come to the pharmacy and present a unique validation code). The pharmacy must supply the medicine with reasonable promptness, or give an estimate of when supply can be made and paragraph 8 of schedule 4, subparagraphs 5-10, apply to these PTP supplies (national formulary, quantity, strength or dosage not stated, minimum pack size, special container

and original pack). 8(b) There are also relevant provisions for refusal to supply under a PTP, including where supply is contrary to the pharmacist's clinical judgement.

- a) The second, the '**Decision tree**' now for **EPS**. Schedule 4, paragraph 9, 2A states that *P may refuse to provide a drug or appliance ordered on an electronic prescription if the access that P has to the Electronic Prescription Service is not such as to enable P to dispense that prescription promptly (or at all)...*[and the proposed addition is] *but where P does, P must take all reasonable steps to ensure the product ordered by the prescriber is supplied within a reasonable timescale, which may require (depending on what steps or combination of steps the circumstances require) ' – there then follows a list of activities – providing to the patient with details of local pharmacies which may be able to supply, urgent supply with Rx, urgent provision of a non-electric Rx and arranging delivery or for later collection by the patient's representative. The decision tree is applicable if there is no EPS available to the pharmacy, it is not applicable for each individual medicine shortage, which NHSE&I and DHSC has proposed originally.*
7. The subcommittee agreed this aspect of the changes but expressed concern that the decision tree involved delivery of a medicine. It was considered that delivery has not been and should not be included in the Terms of Service (other than as part of DSP requirements separate to Schedule 4); also that the provision was not appropriate for DSPs because it suggested collection of a dispensed medicine from DSP premises, and under the regulations DSPs are not permitted to provide essential services on the pharmacy premises. For these two reasons it was considered that this final provision should be deleted.
8. The third, the **Flexible provision of relevant immunization services during a pandemic**. This allows NHSE&I to agree, on application, a specified period within a pharmacy's core or supplementary hours when limited pharmaceutical services may be provided, for example when only flu vaccinations might be given. For coronavirus and flu, NHSE&I may give a general notice of what is permitted.
9. The fourth, **facilitating remote access**. If a pharmacy decides to provide pharmaceutical services by remote access (and this applies to all DSPs and, on a patient basis B&M pharmacies) the pharmacy must, to a reasonable extent, facilitate the provision of pharmaceutical services to the patient; and must establish, maintain, and keep under review procedures to facilitate that remote access. Essentially this is confirmation or clarification that a pharmacy must provide essential services to remote patients who are provided with dispensed medicines. Arguably, this is already clear from the Terms of Service.

Action 1

10. To recommend to the Committee the four changes to NHS regulations considered, with one caveat that delivery should not be referenced in the regulations; and inform NHSE&I

Consultation on proposed changes to the Human Medicines Regulations relating to COVID-19 and flu

11. The subcommittee noted key proposed changes to the Human Medicines Regulations to give Government comprehensive options for the supply and administration of medicines, including vaccines in response to a pandemic, including the current ongoing response to COVID-19 and flu. This included:
 - a) Provide exemptions from the need for wholesale dealers licences for the supply of a medical product used for the vaccination or immunisation of coronavirus or influenza virus, subject to certain conditions
 - b) Authorise wholesale supplies to any person who may administer a POM by virtue of a protocol relating to coronavirus and influenza virus, subject to conditions;
 - c) Provide conditions for temporary authorisation of medicines, subject to conditions;
 - d) Expand the scope of Patient Group Directions (PGD) (**including those for pharmacy**) to include unlicensed vaccines;
 - e) Provide for the supply and administration of coronavirus and influenza vaccination or immunisation in certain occupational health schemes, subject to conditions;
 - f) Provide that other persons (**which could include pharmacy technicians**) may administer a coronavirus and influenza vaccinations;
 - g) Revise the provision relating to supply in the event of a pandemic (supply of a POM without a prescription);
 - h) Introduce protocols relating to administration of coronavirus and influenza vaccinations – in broad terms condition A – for treatment where there is a pandemic, or it is anticipated imminently, and there is a serious risk or potentially a serious risk to human life, B - supply or administration is in accordance with a protocol approved by the Secretary of State or appropriate Minister in the devolved countries, C - protocol specifies persons to administer, process by which classes of person of a specified class is designated to administer, recording of administration requirements; D - appropriate temporary or permanent marketing authorisation
 - i) Allow advertisements and promotional material of temporarily approved medicines in related specified circumstances;
 - j) Provide that temporarily approved medicines may be classified as POM or a product that is only available from a pharmacy.

12. The subcommittee agreed that the PSNC response should be to support the proposals and indicate that the BAU - medicine supply chain and administration of any coronavirus vaccine by community pharmacy - offer more reliability and established patient safety on vaccinations and also, that patients and the public will naturally turn to those from whom they obtain medicines and advice and who are readily accessible on the High Street.
13. It was clarified that the proposed provisions will allow for any authorised person under a Pandemic Treatment Protocol (under proposed Regulation 247A) to administer a vaccine (which may be for coronavirus disease of influenza) and so could include any member of pharmacy staff, not just pharmacy technicians.
14. It was also asked whether the Government safety net insurance as part of the national response to COVID-19 would cover contractors and it was indicated it should do so, for example, if part of an NHS service, carried out by pharmacy staff, is in response to the COVID-19 outbreak and a contractor's own indemnity insurance did not cover it, but this would be confirmed with DHSC.
15. The general view was that the provisions were pragmatic

Action 2

16. **Respond to the consultation as agreed and confirm the Government's safety net indemnity insurance will cover contractors supplying and administering vaccines as part of an NHS pharmaceutical service – a Pandemic Treatment Protocol – under section 247A of the Human Medicines Regulations 2012.**

AOB

17. There were no AOB items.

No.	Action	Responsible
Action 1	To recommend to the Committee the four changes to NHS regulations considered, with one caveat that delivery should not be referenced in the regulations; and inform NHSE&I	GH
Action 2	Respond to the consultation as agreed and confirm the Government's safety net indemnity insurance will cover contractors	GH

	supplying and administering vaccines as part of an NHS pharmaceutical service – a Pandemic Treatment Protocol – under section 247A of the Human Medicines Regulations 2012.	
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