Pharmaceutical Services Negotiating Committee Agenda

for the meeting to be held on 5th September 2019

at CCT Venues Barbican, 135-137 Aldersgate Street, Barbican, EC1A 4JA

Commencing at 9am

Members: Richard Bradley, David Broome, Mark Burdon, Peter Cattee, Ian Cubbin, Marc Donovan, Samantha Fisher, Mark Griffiths, Alice Hare, Jas Heer, Tricia Kennerley, Clare Kerr, Sunil Kochhar, Andrew Lane, Margaret MacRury, Fin McCaul, Has Modi, Lucy Morton-Channon, Garry Myers, Bharat Patel, Indrajit Patel, Prakash Patel, Umesh Patel, Jay Patel, Janice Perkins, Adrian Price, Sian Retallick, Anil Sharma, Stephen Thomas, Faisal Tuddy, Gary Warner

Chairman: Sue Killen

1.	Welcome from Chair	**09:00 – 09:30**
2.	Apologies for absence	
3.	Conflicts or declaration of interest	
4.	Minutes of the May meeting	
5.	Matters Arising	
Action:		
7.	Chairman's Report and Chief Executive's Report	
8.	Transition Payments and Funding update	**09:30 – 11:00**
	Break	**11:00 – 11:15**
9.	"Key issues for Community Pharmacy in England" Guest Speaker – Mark Lyonette, NPA	**11:15 – 12:15**
	Lunch	**12:15 – 13:15**
11.	PQS for 2020/21 FMD following a no-deal Brexit (**Appendix 01/09/2019**) Pharmacy Access Scheme	**13:15 – 15:00**
	Break	**15:00 – 15:15**
12.	Communicating the CPCF	**15:15 – 15:45**
13.	LPC Discussion	**15:45 – 16:15**

13. Feedback from Subcommittees **16:15 – 16:30**

Close **16:30**

Subject	Options for the development of a UK Falsified Medicines System following a no-deal Brexit
Date of meeting	5th September 2019
Committee/Subcommittee	PSNC
Status	Public
Overview	The EU Falsified Medicines Directive (FMD) safety features Delegated Regulation came into force on 9th February 2019. The Government has recently stated that the UK will be leaving the EU on 31st October 2019 whatever the circumstances. In the event of a no-deal Brexit, it is expected that UK stakeholders would no longer be able to comply with the requirement to verify and authenticate packs. The UK Government has however committed to introducing a UK falsified medicines system. This paper is to prompt a Committee discussion on what this scenario could look like.
Proposed action(s)	Consider the options for a UK falsified medicines scheme and decide on a preferred option which could be fed into DHSC and MHRA in the event of a no-deal Brexit.
Author of the paper	Alastair Buxton

Introduction

The EU FMD safety features Delegated Regulation came into force on 9th February 2019. This regulation requires two new safety features (a unique identifier contained in a 2D bar code and an anti-tampering device) to appear on the packaging for almost all prescription only medicines for sale in the European Economic Area (EEA).

Detailed information on FMD can be found at https://fmdsource.co.uk/.

FMD and Brexit

The Government has recently stated that the UK will be leaving the EU on 31st October 2019 whatever the circumstances. In the event of a no-deal Brexit, it is expected that UK stakeholders would no longer be able to comply with the requirement to verify and authenticate medicines via the European FMD system. Therefore, while packs with unique identifiers can still be placed on the market, the legal obligations related to this would be removed for all actors in the UK supply chain.

In the interests of public safety, the Government has already publicly committed to evaluating the options for a future UK falsified medicines regulatory framework, taking into account the investment already made by stakeholders.

It should be noted that there have been several incidents reported across Europe, where the FMD system has correctly identified falsified medicines. It is therefore highly unlikely that the Government will consider removing the requirement for there to be a UK falsified medicines system, but an amended version of the European model is likely to be a viable option.

What could a UK falsified medicines system look like?

Anti-tampering device (ATD)

A UK system could do away with the need for an ATD, but it is hard to create a rational argument to support such an approach. This aspect of the European legislation would therefore be likely to be transposed into UK law. If this happened, there would however be an option to consider UK standards for ATDs. PSNC has received feedback from contractors that many ATDs do not allow the pack to be securely re-closed, once the seal or other ATD has been broken. This presents practical problems for pharmacy teams and patients alike.

Decommissioning products

There are many potential options if consideration of when and how to decommission products starts with a blank sheet of paper, but the Government has indicated that they would wish to be cognisant of the investment in the European FMD system already made by stakeholders in the supply chain.

It is therefore reasonable to assume that the underpinning database structure and system used for the European system and provided by SecurMed in the UK, is likely to be "recycled" or at the very least replicated in any new UK system. That approach would support easier re-use of current FMD equipment across the supply chain.

Consideration can next turn to when a pharmacy may be required to decommission a product before it is supplied to a patient. The current system expects this to be undertaken close to

the time the medicine is supplied to the patient and the '10-day' rule drives compliance with this approach.

Greater flexibility could be introduced in a UK system, for example allowing decommissioning at the point of assembling the prescription or potentially, decommissioning stock on arrival at the pharmacy. Both these options would necessitate not adopting the '10-day rule' within a new UK system.

One of the potential benefits of the current system is its ability to prevent out of date products being supplied to patients and to support accuracy of product selection (in particular reducing the risk of look-alike, sound-alike errors). This benefit would not be available if scanning and decommissioning only occurs at arrival of the product in the pharmacy.

It could however, be possible to re-develop current FMD systems to allow decommissioning on entry, but still allow the data within the 2D barcode to be used by the PMR system for date checking, stock control and dispensing accuracy purposes, where the pharmacy wished to make use of these features.

Data and guidance

Feedback from contractors suggests that there are several aspects of the current FMD system which could be improved and which therefore could be addressed in a UK system. These include:

- The need for management reports from the National Competent Authority (the MHRA in the UK) to be shared with multiple contractors to ensure appropriate support is provided to individual pharmacies within a group. The European legislation does not permit this data to be shared;
- The need for error messages to be rationalised, as there are currently too many query messages which require interpretation, but are unlikely to mean the product should not be supplied to the patient; and
- Linked to the previous point, the need for clearer guidance on what to do when specific alerts are received on scanning a pack. This would also include when stock should be quarantined, what should then happen to the stock, e.g. sending to the National Competent Authority, and the process by which the contractor should be reimbursed for the cost of the quarantined stock.

Committee action

Discuss this topic on tables, exploring:

- what options may be possible in a UK system;
- which elements of the current system would be good to retain, and which could be discarded and why;
- whether there are any additions to the system we would wish to see, e.g. management reports for contractors; and
- what would be the preferred option for contractors?