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## Legislation and Regulatory Affairs Minutes

**Date:** 30 May 2024

**Time:** 2 – 3 pm

**Location:** Teams (Remote)

**Members present:** Ian Cubbin (Chair), Marc Donovan, Lindsey Fairbrother, Ifti Khan.

**In attendance:** Phil Day, Fin McCaul, Jas Heer, Beran Patel, Adrian Price, Mike Dent (Director of Pharmacy Funding), Gordon Hockey (Director, Legal), Suraj Shah (Drug Tariff and Reimbursement Manager), James Wood (Director of Member and LPC Support), Katrina Worthington (Regulations Officer).

**Apologies:** Stephen Thomas.

**Conflicts of interest:** No additional conflicts declared.

**Minutes of the last meeting:** The subcommittee approved the meeting minutes for April 2024.

**Matters arising:** There were no matters arising.

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**ACTION:** ----



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**ACTION: ----**

### CPAF (Community Pharmacy Assurance Framework)

14. The Regulations Officer introduced the paper and indicated that 2 of the 10 screening questions had minor changes from last year: question 15, staffing and smartcards, and 16, business continuity plans for temporary pharmacy closures.
15. She said NHS England will ask pharmacy owners to complete the screening questions in July, those selected for the full questionnaire will be asked to complete it around October, and NHS England and Community Pharmacy England will issue appropriate comms to pharmacy owners on the screening questions.
16. She invited the subcommittee to provide feedback on the proposed changes to the full CPAF questionnaire before the end of June.
17. There was a brief discussion on the overall value of a CPAF process using the same or similar questions as the previous year. It was noted that NHS England considers the process important for assurance purposes. The subcommittee's view was that in future years consideration could be given to asking questions on topical issues or new services, for example, Pharmacy First.
18. The subcommittee endorsed the revised screening questions.

**ACTION: CPAF screening questions to be finalised with NHS England**

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**ACTION:** ----

## AOB

22. The Director, Legal said that new legislation had been laid to severely restrict access to puberty blockers for under 18-year-olds and NHS England will be issuing guidance. The change applies to private prescriptions from Monday 3<sup>rd</sup> June and to NHS prescriptions on 26<sup>th</sup> June, 28 days after the regulations have been laid.

23. From Monday 3<sup>rd</sup> June, next week, EEA private prescriptions, dated on or after the 3<sup>rd</sup>, for puberty suppression in those experiencing gender dysphoria or incongruence, may not be dispensed. There are exceptions for UK private prescriptions. From 26<sup>th</sup> June, similar controls and exceptions will apply to NHS prescriptions.

## Annex

### Original Pack Dispensing

- The legislative amendments to the HMR, will enable pharmacists to have the flexibility to dispense more or less than the prescribed quantity (up to 10% more or less) if that means they can dispense in the manufacturer’s original packs, except where this would negatively affect the patient’s clinical treatment regimen.
- In England, how OPD is provided for in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (PLPS Regs) will have implications on how we reimburse pharmacy contractors.
- The reimbursement arrangements proposed by DHSC are in tandem with the PLPS Regs being amended to say that ‘pharmacists must consider using OPD where appropriate’.

**DHSC propose, under PLPS, OPD applies as set out in the table below:**

Product Type	Yes?	No?
POMs	✓	
Non-POMs (i.e. P-meds, GSLs, no legal category)	✓	
Part IX Appliances	✓	
Controlled Drugs		✓
Unlicensed Specials		✓
Special Containers		✓



## OPD – Reimbursement Proposals

- The NHSBSA will capture the dispensed quantity from the Electronic Reimbursement Endorsement Message (EREM) and will reimburse the quantity in the following scenarios:

Scenario	Reimbursement arrangement
Where the dispensed quantity is the same as the prescribed quantity	Paid as prescribed
Where the dispensed quantity is lower than the prescribed quantity	Paid as supplied
Where the dispensed quantity is up to and including 10% more than the prescribed quantity	Paid as supplied
Where the dispensed quantity is more than 10% of the prescribed quantity	Paid as prescribed

## OPD – Reimbursement Proposals continued

- Paper prescriptions are outside of OPD and would continue to be reimbursed as prescribed.
- Contractors will have to continue endorsing prescriptions as per Clause 9B, Part II of the Drug Tariff (i.e. where the product is not listed in the Drug Tariff or there are multiple pack sizes listed in Category C).
- We would continue to use a price per unit approach where appropriate.
- In line with special containers, if contractors utilised OPD, contractors would not receive the 10p container payment. However, a wider review of Part IV is on the agenda and as such DHSC propose that the 10p container payment is discussed as part of this piece of work.

## OPD IT

- There will be the ability for system suppliers to have notice of the implementation of OPD.
- Once the NHSBSA have been able to work through the rules and requirements, DHSC and NHSBSA would be content to hold a workshop where technical instructions can be further shared, and system suppliers will have the opportunity to raise any questions.