



Standard Operating Procedures for Falsified Medicines Directive operations

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Objectives

These SOPs are designed to ensure that FMD (Falsified Medicines Directive) requirements are followed as part of the pharmacy dispensing and medication handling processes:

1. [Medicine verification and decommissioning](#)
2. [Undo decommissioning](#)

Scope

These SOPs relate solely to the use of the PharmScanner web application (<https://pharmscanner.co.uk>) for fulfilling the healthcare institution's FMD requirements.

The SOPs does not cover how to fulfill these obligations by any other method or software.

Responsibility

Only those members of the team who have been considered competent and listed in the declaration of competence can carry out these procedures.

Review

The SOPs will be reviewed every two years by the responsible person to reflect any changes to legislation affecting the FMD processes.

SOPs should also be reviewed:

- if there is any change in the number of, or competency level of, staff in the institution.
- following any critical incidents.

Associated risks

PharmScanner is a web-based application, and so the organisation should ensure that internet access is consistently available. There is also some hardware required for the FMD dispensing processes, such as 2D bar code scanners; the organisation should ensure that these are available, including spare equipment in case of accidental damage or malfunction.



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Medicine verification and decommissioning

The delegated EU regulations for FMD mean that healthcare institutions, such as clinics, out of hours care and hospitals, are able to decommission medicines as it arrives into their possession. As such, this SOP for verification and decommissioning is to be carried out as the medicines arrive into the institution, as part of the order checking process, before the medicines are put away with existing stock.

1. Gather goods and bring to a computer workstation setup with access to PharmScanner (i.e. a computer with internet access, a 2D barcode scanner, and possibly a label printer).
1. Access/login to PharmScanner - access the PharmScanner web app from the computer web browser, and login using the premises account details (if not already logged in). Click the **Hospital** button on the PharmScanner app.
2. Scan each prescription-only medicine (POM) item - use the 2D barcode scanner attached to the computer to scan each pack which has a 2D data matrix barcode, to verify the pack using PharmScanner. Note that packs which do not have a 2D data matrix barcode do not need to be scanned on PharmScanner.
 - a. PharmScanner will produce an alert if there is an issue detected with a pack that has been scanned:
 - i. If an out of date pack has been scanned, an “out of date” alert will appear. In this case, remove the out of date item from the basket and set aside to be processed as per your medication disposal or wholesaler return procedure (as appropriate).
 - ii. If a pack scans and then the status is **Unknown** then this means that the pack is not in the product database, and it cannot be determined if the pack is legitimate, or if it is not legitimate. As such, it will be a choice for the Responsible Pharmacist or Person to decide whether the pack can be used or not, as long as they can justify their actions, by considering for example which supplier the medication has been purchased from.
 - iii. If the pack scans and the status is **Inactive** then this means that the pack cannot be used. Clicking on the entry for this pack in the current basket, will show more details in the “Product Details” window, in the “Reason” field:



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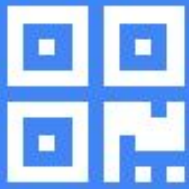
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1. If the reason is RECALLED or WITHDRAWN then do not use the pack and instead follow existing SOPs for dealing with recalled medication.
2. If there is any other reason (such as SUPPLIED, DESTROYED, LOCKED, EXPORTED, SAMPLE, STOLEN, CHECKED_OUT, FREESAMPLE) quarantine the suspicious pack and set aside to be processed as per your existing SOPs for dealing with suspected counterfeit medicines.
3. Check each item - for each item that was scanned in step 4, perform a visual check of that pack to make sure that if there is an anti-tamper device (ATD), that it has not been damaged. Note that if the pack does not have an ATD, then you would therefore not be required to check that it is intact.
 - a. If any of the scanned packs have a damaged ATD, check the computer screen for the PharmScanner app to see if the pack has previously been dispensed. If so, this may suggest that the pack has previously been “split” in another dispensing session.
4. Once all packs have been scanned and physically checked, then click the **DECOMMISSION** button; press the confirm action and wait for the response to ensure that the packs have been successfully decommissioned.

Undo decommissioning

In some cases, it may be necessary to undo decommissioning of a pack of medication. For example, a pack of medication is to be returned to the wholesaler after being ordered in error; this action can be performed in PharmScanner within 10 days of the initial decommissioning.

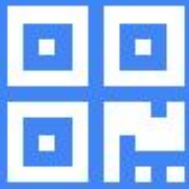
1. Take the pack(s) to be recommissioned to a computer workstation setup with access to PharmScanner (i.e. a computer with internet access, a 2D barcode scanner, and possibly a label printer).
2. Access/login to PharmScanner - access the PharmScanner web app from the computer web browser, and login using the premises account details (if not already logged in). Click the **Hospital** button on the PharmScanner app.
3. Scan each pack which is to be recommissioned. Upon successful scan, the item will appear in the “Goods-In List”.



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4. Once all packs are scanned, click the **UNDO DECOMMISSION** button; press the confirm action and wait for the response to ensure that the packs have been successfully recommissioned.



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SOP authorisation

	NAME	TITLE	SIGNATURE	DATE
EDITOR				
REVIEWER				
AUTHORISER				

Declaration of competence

Name	Signature*	Date

*By signing this declaration you are confirming that:

- You have received the necessary training as outlined within this SOP'
- You have read and understood the information within this SOP'
- You will comply with the SOP at all times as directed.