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 aggregation
2. Medicine decommissioning
3. Undo decommissioning
4. Destroy medication

Scope

These SOPs relate solely to the use of the PharmScanner web application (https://pharmscanner.co.uk) for fulfilling the pharmacy FMD requirements.

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

Responsibility

Only those members of the pharmacy 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 pharmacy superintendent 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 pharmacy.
- 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.

Medicine verification and aggregation

The FMD process for medicine verification and aggregation is to be carried out after the prescription labelling process, and before the prescription assembly process.

1. Gather stock and prescriptions - after the prescription has been labelled, ensure that all prescription forms and items for dispensing are together in a basket, 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).
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 **Dispense** button on the PharmScanner app.
3. Assess if the current prescription has already been partly dispensed (e.g. if you are making up "owings" for this prescription).
   a. If some of the items for this prescription have already been assembled (i.e. the medication labels have already been stuck onto some of the items) then "load" this existing PharmScanner "basket" by scanning the existing PharmScanner bag label, PMR bag label, or EPS prescription barcode.
   b. If none of the prescription items have already been assembled, then you do not need to "load" an existing basket.
4. Scan each prescription-only medicine (POM) item - use the 2D barcode scanner attached to the computer to scan each item for this prescription which has not yet been assembled and also 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). You will need to get another pack of this prescription item from the dispensary to fulfill this prescription.
      ii. If a pack status is "recalled" or "withdrawn" then an alert with this message will appear. In this case, do not use the pack and instead follow existing SOPs for dealing with recalled medication; you will need to get
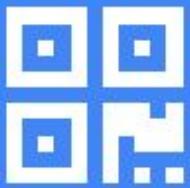
another pack of this prescription item from the dispensary to fulfill this prescription.

    iii.   If an alleged counterfeit pack has been scanned, a "counterfeit warning" alert will appear. In this case, remove the suspicious pack from the basket and set aside to be processed as per your existing SOPs for dealing with suspected counterfeit medicines. You will need to get another pack of this prescription item from the dispensary to fulfill this prescription.

5. 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.

        i.   If the damaged pack has not been previously dispensed with PharmScanner, then set this pack aside to be returned to the respective wholesaler as per your returns procedure. Click on the relevant pack entry on PharmScanner, and click the **REMOVE PRODUCT** button to remove it from the PharmScanner "basket". You will need to get another pack of this prescription item from the dispensary to fulfill this prescription.

6. Process MDS and split packs - packs that are going to be split to be put into an MDS/compliance aid, and packs that are being split to make up this prescription, both need to be decommissioned at this point. To do so, select each pack in the list of items in the "basket" that is to be split, and press the **MDS/SPLIT PACK** button.

7. **SAVE & BAG** or **MARK AS COLLECTED** - if the prescription is in a basket to indicate that the patient is currently waiting, then click the **MARK AS COLLECTED** button; otherwise, click **SAVE & BAG**.

    a.   Clicking **SAVE & BAG** will aggregate the prescription items, and bring up the **SAVE & BAG** popup. Scan each EPS prescription barcode and PMR barcode bag label (if available); if neither of these are available then click **PRINT BARCODE** and print an aggregate barcode label, and put this into the prescription basket with the prescription form(s) and prescription item(s).
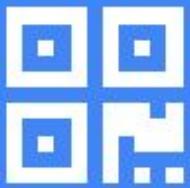
Medicine decommissioning

Medication must be decommissioned at the point of supply - either when the patient or their representative collects it, or when it is about to be delivered.

- If the medication is being collecting, then the decommissioning should take place immediately after the prescription transfer checks (e.g. confirming the correct patient, prescription, exemption or payment details etc).
- If the medication is being delivered, then the decommissioning should take place just before the medication is handed to the delivery driver, or being placed in the area designated for prescriptions which are due to be delivered on the next route.

1. Take the prescription 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).
3. Scan the aggregate barcode label for this prescription; remember that this may be any one or more of the following:
   a. An EPS prescription barcode
   b. A barcode on a PharmScanner printed bag label
   c. A barcode on a PMR bag label
4. On successful barcode scan, PharmScanner will load the prescription "basket" and re-verify all packs on the computer screen.
   a. If there is a problem re-verifying any of the packs, then an alert will appear. Depending on the alert, follow the instructions in Medicine verification and aggregation
5. If any packs are to be removed (e.g. the patient collecting does not wish to have one of the items on the prescription) then they can be removed at this stage: to remove a pack, select it in the list of items in the current basket, and then click **REMOVE PRODUCT**. A confirmation window will appear; click **CONFIRM** and the pack will be removed from the "basket". You can then put this pack of medication back into the dispensary stock, following your existing SOPs for this process.
6. Finally, click the **MARK AS COLLECTED** button to decommission the "basket" of medication. A confirmation window will appear; click **CONFIRM** and wait for the confirmation message that the basket has been successfully decommissioned.
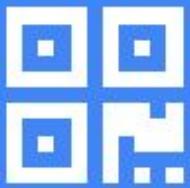
Undo decommissioning

In some cases, it may be necessary to undo decommissioning of a pack or a "basket" of medication. For example, a medication delivery has failed because the patient was not at home to receive the prescription, and so the prescription has been brought back to the pharmacy.

1. Take the prescription 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).
3. Scan the aggregate barcode label for this prescription; remember that this may be any one or more of the following:
   - An EPS prescription barcode
   - A barcode on a PharmScanner printed bag label
   - A barcode on a PMR bag label
4. On successful barcode scan, PharmScanner will load the prescription "basket" and re-verify all packs on the computer screen.
   - If there is a problem re-verifying any of the packs, then an alert will appear. Depending on the alert, follow the instructions in Medicine verification and aggregation
5. To undo the bag/"basket" decommissioning, click the UNDO DECOMMISSION button. A confirmation window will appear; click CONFIRM and wait for the confirmation message that the basket has been successfully recommissioned.
   - If there is a problem with this process, then an alert will appear. Note that if the "basket"/bag was decommissioned more than 10 days ago, then it is not possible under the FMD regulations to undo the decommissioning - in this case, the packs of medication which have been decommissioned are not to be reused.

Destroy medication

Occasionally, it may be necessary to quarantine prescription-only medicines (POMs) for destruction from stock already held within the pharmacy. For example, a bottle of liquid medication has become damaged and is leaking, and hence is to be placed in a medicine waste container to be collected and disposed of by incineration. Note that this SOP applies only to medication that was already within the pharmacy stock, and not to patient-returned medication (from this pharmacy or any other pharmacy).
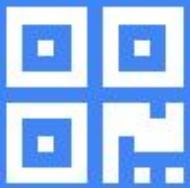
1. Take the pack/packs to a computer workstation setup with access to PharmScanner (i.e. a computer with internet access, a 2D barcode scanner, and possibly a label printer).
2. Access/login to PharmScanner - access the PharmScanner web app from the computer web browser, and login using the premises account details (if not already logged in).
3. Scan each prescription-only medicine (POM) item that is to be destroyed - use the 2D barcode scanner attached to the computer to scan each item 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.
4. Once all packs have been scanned, click the "Tools" dropdown menu at the top of the page, then click "Misc. Operations". This will enable the additional buttons, **DESTROY** and **SAMPLE** underneath the **MARK AS COLLECTED** button.
5. Click the **DESTROY** button, and the selected packs will be marked as destroyed. Confirmation of this action is seen when each pack in the "Current Basket" has the "Status" changed to "Destroyed".
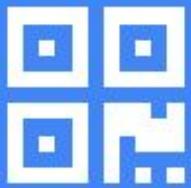
SOP authorisation

	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.