Objectives

These SOPs are designed to ensure that FMD (Falsified Medicines Directive) requirements are followed as part of the wholesale distributor's processes:

1. Designated wholesaler(s) lookup
2. Medicine verification
3. Medicine decommissioning
4. Undo decommissioning
5. Destroy medication
6. Business continuity plan

Scope

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

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

Responsibility

Only those members of staff 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 Peron (RP) to reflect any changes to legislation affecting the FMD processes.

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 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.

Designated wholesaler(s) lookup

As per the delegated FMD regulations, wholesalers are not required to verify packs of medicine if they have been received directly from the manufacturer, or from a wholesaler holding the Marketing Authorisation or from a wholesaler who is designated (with a written contract) by the manufacturer to distribute the products on their behalf. PharmScanner has functionality to check the information provided by the product Marketing Authorisation Holder to assist wholesalers in deciding whether or not they are required to verify the products they are receiving.

1. Gather a pack of the product that you want to check the list of designated wholesalers for, 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 **Wholesale** button on the PharmScanner app, and then choose the "Mixed Wholesale" option.
3. Scan the pack of medicine using the 2D barcode scanner. On successful scan, the product will appear in the "Current Lot" table. Click on the entry for the product to load the "Product Details" window. In the "Product Details" window, there will be listed the names of the Designated Wholesaler(s).

Medicine verification

The FMD process for medicine verification should be carried out immediately after the "receipt of medicinal products" process (i.e. after the goods have already been inspected for damage and after the consignment documentation has been reconciled against the goods that have been received) but before the goods have been relocated to their storage area.

Note that medicine verification can be performed on a risk-based basis: for example, goods arriving at the wholesale business directly from the manufacturer do not need to be verified, whereas goods which are received as "returns" from a customer must be verified. In the case of returns, the medicine verification process should occur immediately after the "return of medicinal products to inventory" process (i.e. after all necessary "returns" documentation has been processed and the products have been physically inspected and found to be unopened and in good condition).
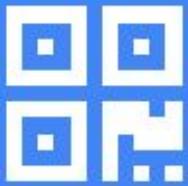
1. Gather goods and bring to a computer workstation setup with access to PharmScanner (i.e. a computer with internet access, a 2D barcode scanner, and possibly a label printer).
2. Access/login to PharmScanner - access the PharmScanner web app from the computer web browser, and login using the premises account details (if not already logged in).
3. For each single batch of prescription-only medicine (POM), scan the 2D barcode (data matrix) on every pack. 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 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 a 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:
         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) then do not use this pack and set aside to be processed as per your existing SOPs for dealing with suspected counterfeit medicines.
4. Physically 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
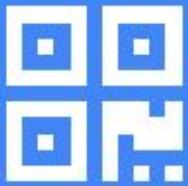
not been damaged. Note that if the pack does not have an ATD, then you would therefore not be required to check that it is intact; also note that if the packs were already assessed for damage (including whether their ATD is damaged) as part of the "receipt of medicinal goods" or "return of medicinal products to inventory" process, then you do not need to repeat this step.

    a. If any of the scanned packs have a damaged ATD, 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 "Current Lot".

5. Once all packs have been scanned and physically checked, then select "Verify" from the "Select Operation" dropdown menu, and then click the **PERFORM OPERATION** button, and wait for the verification response from the PharmScanner server.

6. Once PharmScanner has finished attempting to verify the packs, the status of each pack will be displayed in the "Status" column of the "Current Lot" table. PharmScanner will produce an alert if there is an issue detected with a pack that has been scanned:

    a. Handle any alerts message by following the guidance in the Medicine verification SOP.

7. Clicking **LINK TO AGGREGATE LABEL** will allow you to save this "lot" of verified medicines against an existing barcode (e.g. if there is already a barcode on an outer container of these packs) or to generate a label with a QR code that can be scanned to load up the "lot" again:

    a. To use an existing barcode, scan each barcode that you wish to use.

    b. To print a label, click the **PRINT BARCODE** button; you can then attach this to an outer container for this specific batch/lot of medication.

Medicine decommissioning

When supplying POMs to a customer who is exempt from FMD obligations (i.e. Article 26 exemptions) then it may be necessary to decommission these packs of medication before delivery. Medicine decommissioning should occur during the "order processing, picking and despatch" process: after the packs have been picked from the warehouse as per the product pick list, but before invoicing or packing.
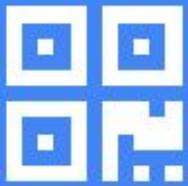
1. Gather packs of medication in a picking basket and bring to a computer workstation setup with access to PharmScanner (i.e. a computer with internet access, a 2D barcode scanner, and possibly a label printer).
2. Access/login to PharmScanner - access the PharmScanner web app from the computer web browser, and login using the premises account details (if not already logged in).
3. 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. Note that packs which do not have a 2D data matrix barcode do not need to be scanned on PharmScanner.
   a. Use the same instructions as in [Medicine verification](#) to decide if any of the packs are inappropriate for supply.
4. 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, then set this pack aside to be quarantined and investigated as per audit procedures. 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 storage area to fulfill this order.
5. Once all packs have been processed, click the **SAVE & BAG** button to allow you to save this "basket" of medicines for delivery against an existing barcode (e.g. if there is already a barcode on some delivery documentation or picking list) or to generate a label with a QR code that can be scanned to load up the "basket" again:
   a. To use an existing barcode, scan each barcode that you wish to use.
   b. To print a label, click the **PRINT BARCODE** button; you can then attach this to an outer container or documentation for this specific delivery of medication.
6. **CLOSE** the "Save & Bag Basket" popup, and then click the **MARK AS COLLECTED** button, which will decommission all of the packs within the current PharmScanner "basket".

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 to a customer who is exempt from FMD obligations (e.g. Article 26 exemptions) has failed, and so the order has been brought back to
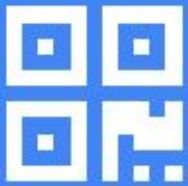
the wholesaler premises. If the medication is not going to be re-delivered to the same customer within 10 days, then the affected packs should be recommissioned and put back into the wholesaler inventory

1. Take the basket/delivery 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 delivery; remember that this may be any one or more of the following:
   ○ A barcode on the original delivery documentation, e.g. picking list.
   ○ A PharmScanner barcode label generated as part of the decommissioning process.
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
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"/delivery 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 wholesaler's inventory. For example, POMs which have been returned to the wholesaler from customers, but rejected for reuse/putting back into saleable inventory due to e.g. unacceptable damage.

This "destroy medication" process should be carried out before the "waste management of medicinal products" SOP: after the packs for destruction have been moved to the designated area for "rejects" or destruction, but before details of the products have been recorded into the Rejected Products Log (so that, where applicable, the Rejected Products Log can be modified
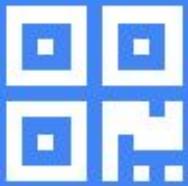
to include a field recording whether the product has been marked as destroyed on PharmScanner).

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. 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".

Business continuity plan

As per the delegated FMD regulations, a backup system is provided for users in the case of an emergency, i.e. when the PharmScanner system is unavailable. This interface is referred to as the "web GUI". To use the web GUI, the wholesaler must first download their access credentials from the PharmScanner website - for this reason, **it is highly recommended that wholesalers download and keep safe their access credentials** in case of the unlikely event that the PharmScanner website becomes inaccessible.

This SOP details how to obtain access to the web GUI in case of emergency; further details of how to use the web GUI may be available from

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).
2. Visit the PharmScanner "Settings" page, using the link at the top of the page.
3. On the "Settings" page, locate the **NMVS Credentials** section. Make a note of the NMVS username, NMVS password, and certificate passphrase. Click on the **DOWNLOAD CERTIFICATE FILE** button to download your certificate file.
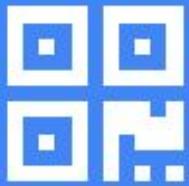
4. Install your certificate file onto your computer; you can generally accomplish this by opening (double-clicking) the certificate file to start the installation process, and then follow the on-screen steps to complete the process. You will be prompted to enter your certificate passphrase (obtained in the previous step) in order to complete installation of your certificate file.

5. Once your certificate has been installed, you can access the web GUI by visiting https://portal-prod-uk.nmvs.eu/NMVS_PORTAL in your web browser and selecting your certificate when prompted. You will then be able to log in using your NMVS username and NMVS password obtained in step 3.
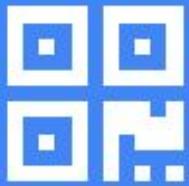
SOP authorisation

	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.