UKFMD
Working Group for Community Pharmacy

FMD interim guidance from the UK FMD working group for community pharmacy

Version 1, 7/2/2019

This guidance on dealing with FMD alerts is interim. Updated versions will be available from FMDsource.co.uk here http://bit.ly/FMDscan

The final phase of FMD implementation begins on 9th February 2019

FMD is a huge project and it is important that during the initial period that medicines are not unreasonably withheld from patients, unless there is a high degree of suspicion that the pack might be falsified.

At present, there are not many FMD-compliant packs in pharmacies. We know that some generic medicine packs that have a 2D data matrix are not actually FMD-compliant packs (one indication is that they do not have an anti-tampering device). If you scan them the system will generate an alert. More information on identifying FMD- compliant packs is available on pages 1 to 10 of http://bit.ly/FMDpacks

In the initial phase of implementing FMD many "false positive" alerts are expected. This does not necessarily indicate a falsified medicine, and in most cases it will be appropriate to dispense the medicine, subject to the normal checks. The alerts will reduce in number as more of the packs reaching pharmacy are FMD-compliant.

The most common alerts seen in community pharmacy are likely to be:

- **Unknown product code** (NMVS_NC_PC_01) – mainly due to 2D barcodes on pre-FMD packs or FMD packs, where the manufacturer has not uploaded the data
- **Failed to find batch** (NMVS_FE_LOT_03) – probably due to manufacturers not uploading relevant batch data through the European Hub (EMVS)

The table on page 2 shows the most relevant alerts and the text that may be displayed. It offers guidance to superintendents and responsible pharmacists on how to respond. Ultimately professional discretion will be required.

When revising your SOPs, refer to the RPS professional guidance on FMD
https://www.rpharms.com/resources/ultimate-guides-and-hubs/fmd#alerts
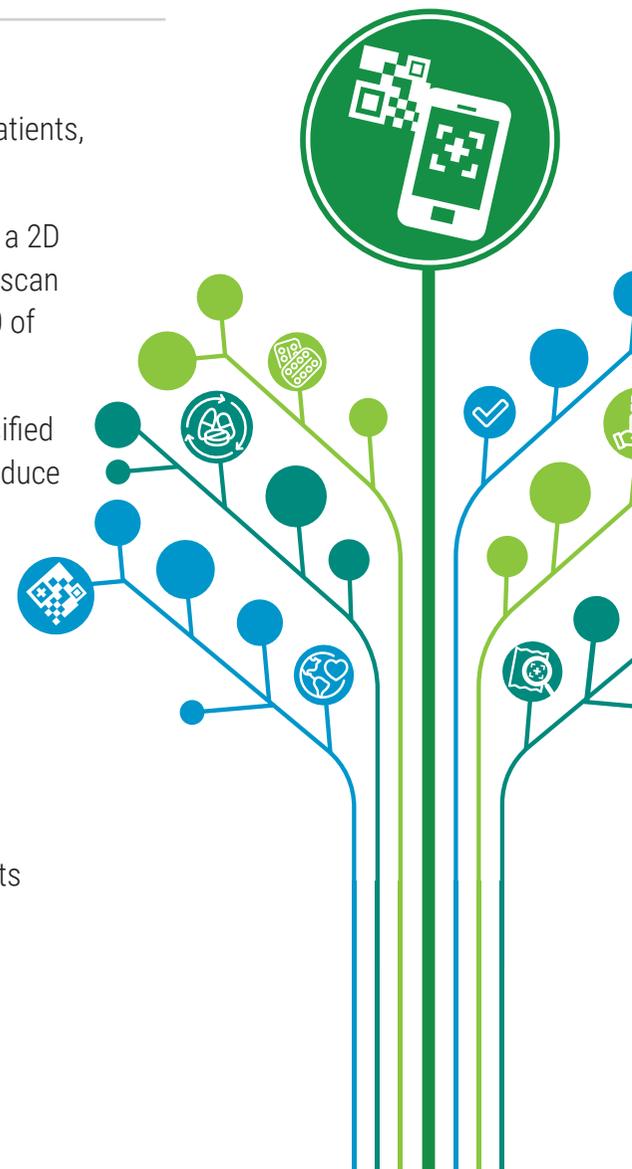
Message sent by National Medicine Verification System Return Code, Description, Short Description	Brief explanation	Suggested guidance and interpretation
NMVS_NC_PC_01, **Unknown product code**, Unknown product	This product code was not found in the system.	Pack not in system. Supply after normal checks.
NMVS_FE_LOT_03, **Failed to find a batch for the given data,** Unknown batch designation	The batch number was not found although the product code exists.	Pack not in system. Supply after normal checks.
NMVS_FE_LOT_12, **Expiry date does not match the date held in the NMVS,** Expiry date missmatch	The product code and batch number were found but the expiry date does not match the database. Note: there is a known issue with the system that can trigger this alert incorrectly.	QUARANTINE pack. EXPIRY DATE is INCORRECT. Refer to SOP
NMVS_FE_LOT_13, **The batch ID does not match the serial number in the NMVS**, Batch number mismatch	The product and serial number were found and match but the batch number is incorrect.	QUARANTINE pack. BATCH number is INCORRECT. Refer to SOP
NMVS_NC_PC_02, **Unknown serial number,** Unknown pack	Product code was found, batch number was found, expiry date does match, but the serial number is unknown.	QUARANTINE pack. SERIAL NUMBER is INCORRECT. Refer to SOP.
NMVS_NC_PCK_06, **Actual pack status doesn't match the undo transaction (set and undo status must be equivalent)**, Invalid status	The attempted undo does not match the existing status of the pack.	QUARANTINE pack. The WRONG UNDO transaction has been used
NMVS_NC_PCK_19, **Property is already set on pack,** Invalid status	The pack is already set to the status that has been requested in this transaction. Note: Non-UK pack.	QUARANTINE pack. Pack INACTIVE. Refer to SOP. Non-UK pack.
NMVS_NC_PCK_20, **Defined timeframe between setting this property and the undo was exceeded,** Timeout	Undo attempted beyond the 10 day recommissioning limit.	10 day recommissioning LIMIT exceeded. Refer to SOP.
NMVS_NC_PCK_21, **Undo can only be executed by the same user who previously set the attribute,** Undo not possible	Undo transaction can only be executed by the same user (location and credentials).	Pack was issued at another location/credentials. Unless you have a dispensary and a WDL, QUARANTINE pack. Refer to SOP. Non-UK pack
NMVS_NC_PCK_22, **Pack is already inactive,** Invalid status	Double dispense limit exceeded or already decommissioned by another user.	Pack decommissioned many times. Unless this was at your site, QUARANTINE PACK. Refer to SOP
NMVS_NC_PCK_27, **Status change could not be performed,** Status change unable	The attempted undo does not match the existing status of the pack. Note: Non-UK pack.	QUARANTINE pack. Refer to SOP. The WRONG UNDO transaction has been used. Non-UK pack.

SOP = Standard Operating Procedure for handling FMD-related alerts and error messages and reporting suspected falsifications to National Competent Authority (i.e. MHRA) as and when necessary