UKFMD
Working Group for Community Pharmacy

# Scanning packs – what to look for

## Implementing the EU Falsified Medicines Directive in the UK

# FMD – what the “right” packs look like

# FMD safety features – what to look for

**2D data matrix**

[printed on low-reflecting area]

**Anti-tampering device**

[various different kinds can be used]

**Human-readable text**

[Product code or GTIN – may be pre-printed]

[Serial number] [Expiry date] [Batch or lot number]

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# FMD safety features – 2D data matrix

- Normally on end of pack
- Normally next to human-readable text items
- Only one 2D data matrix allowed on each pack

- Sometimes printed on different part of pack

# FMD safety features – 2D data matrix

- Can be printed in reverse (white-on-black/colour)
- Scanners need to be set to recognise this format

- Seals or stickers should not obscure 2D matrix

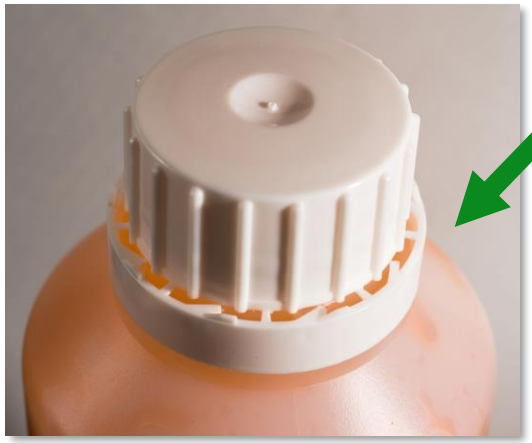
# Examples of anti-tampering devices

**Seals or stickers**

[with or without holograms]

**Pack glued shut**

[with perforations]



**Twist to open**

[with device visible]

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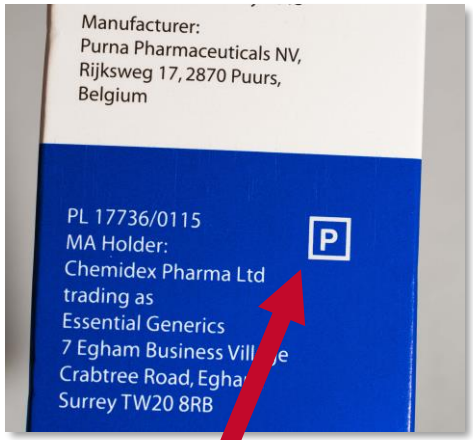
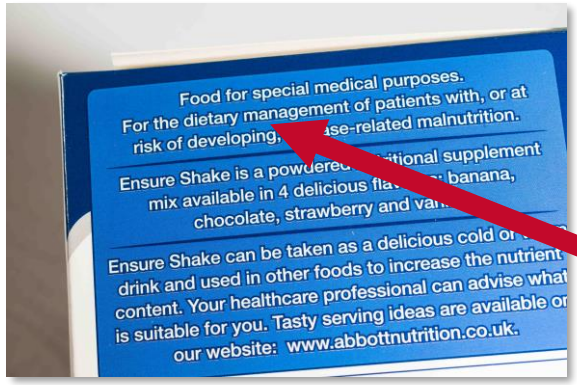
# FMD – what the “wrong” packs look like

# Out-of-scope – do not need to be authenticated




**Non-prescription**
[Pharmacy (P)]
[General Sale List (GSL)]




**Not a medicine**
[Specialist foodstuffs]

**Medical device**
[with CE marking]

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# Older stock (without safety features) can still be used

**No 2D data matrix**
[with or without anti-tampering devices]

**No serial number**
[with or without 2D data matrix]

**No anti-tampering device**
[with or without 2D data matrix and serialisation]

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# Other types of barcode (not FMD)

**QR code**

[note three squares in corners of code]

**Linear barcode**

[pre-printed]

# FMD error and alert messages

# FMD – error and alert messages (for pharmacy and wholesale)

NORMAL (POSITIVE) RESPONSE

Confirmation
Green light
[System live]
Single "beep"

WHOLESALE (excluding Article 23)

DISPENSING POINTS

Decommissioning of packs during dispensing or hand-over (can use consolidated bag label codes)

Actions
Handle and supply as normal. Hand over to patient or customer

BAD (NEGATIVE) RESPONSES

Based on pack coding

NOT FMD
(OTC, pre-FMD stock, medical device, non-medicine)

Confirmation
Amber light
Single "beep"

FAILS TO SCAN
(Damaged pack or barcode)

No sound
Move to manual data entry process

MANUAL DATA ENTRY

YES

Data OK?

NO

Action
As required (see bad responses)

Based on pack data

OUT OF DATE
(Beyond expiry date)

Confirmation
Red light
Single "bong"

Warning message
"Pack <NAME/UI> has expired. Do not dispense. Follow SOP for disposal of pack"

Action
Disposal or destruction of expired stock as per current SOP. Stock file adjustment and re-order if required

DOUBLE SCAN
(More than one scan in same location in quick succession)

Confirmation
Red light
Single "bong"

Warning message
"This pack <NAME/UI> has been scanned twice in this pharmacy and was last scanned at <DATE/TIME>"

Action
Staff to acknowledge message, then dispense as normal (unless limit reached)

DOUBLE SCAN LIMIT

Limit reached?

NO

YES

RECALLED PACK
(Pack recalled or withdrawn)

Confirmation
Red light
Double "bong"

Alert message
"Pack <NAME/UI> was [recalled/ withdrawn]. Do not dispense. Follow SOP for return or disposal"

Action
Return or disposal of recalled or withdrawn stock as current SOP. Stock file adjustment and re-order if required

Based on response from NMVS

STATUS ERROR
(Pack status marked as stolen, free or NCA sample, exported, destroyed or checked-out)

Confirmation
Red light
Double "bong"

Alert message
"There is a problem with pack <NAME/UI>. Do not dispense. Follow FMD SOP for investigations"

DATA ERROR
(Data on pack does not match NMVS records, has missing fields or incorrect characters)

Confirmation
Red light
Double "bong"

Alert message
"There is a problem with pack <NAME/UI>. Do not dispense. Follow FMD SOP for investigations"

Action
FMD SOP: Quarantine and mark stock (alert ID) and start internal investigation. Inform NCA as required

Investigation
Internal governance investigation. Inform NCA as soon as possible using FMD alerts portal or hotline

ALREADY USED
(Pack already decommissioned in another location or country)

Confirmation
Red light
Double "bong"

Alert message
"Pack <NAME/UI> already used in another place. Do not dispense. Follow FMD SOP for investigations"

PACK LOCKED
(Pack status marked as locked)

**KEY AIMS**

- Minimise messaging for positive responses
- Messages = problem (plain text) + action
- Messages, warnings and alerts are unambiguous and not reliant on colours alone
- Consistency and clarity of messaging (within each state or language)
- Consistency of actions (at least within organisations)
- Clarity of reporting and investigations (when/ urgency, to whom, how, what to report)
- Clear impact from bad messaging (stops labelling or handover)
- TERMINOLOGY: "Alert" = message from NMVS to end user "Warning" = message from local system

Note: Pack <NAME/UI> data taken from pack coding and/or master data

Walgreens Boots Alliance

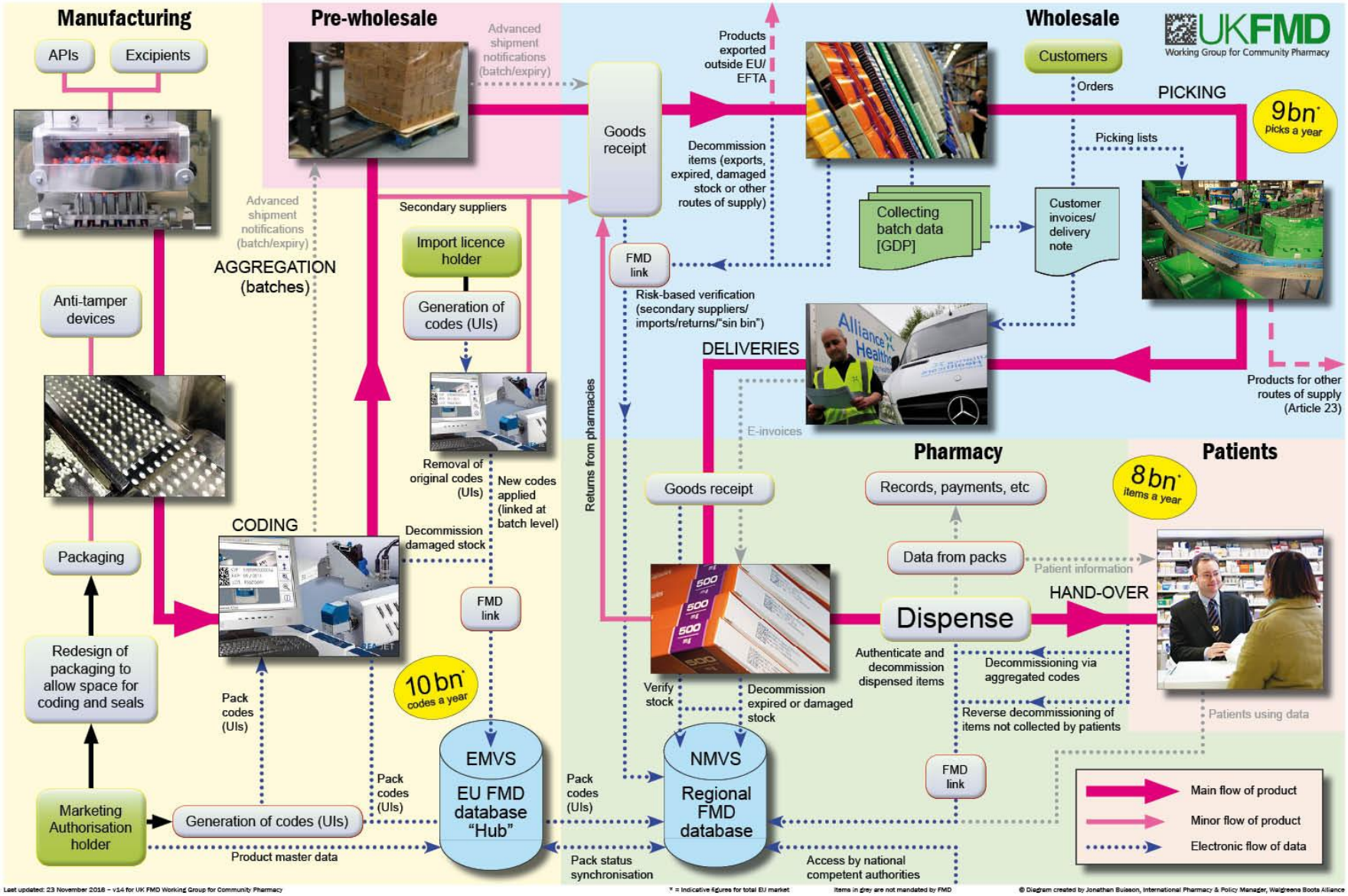
Last updated: 23rd October 2018 – v5a (updated for publication)

References: Naughton B et al. BMJ Open. 2016 Dec 1;6(12):e013837 and BMJ Open. 2017 May 6;7(5):e013838.

© Diagram created by Jonathan Buisson, International Pharmacy & Policy Manager, Walgreens Boots Alliance

# The journey of a patient pack

# European Falsified Medicines Directive (2011/62/EU) and Delegated Regulation (2016/161)




Last updated: 23 November 2016 – v14 for UK FMD Working Group for Community Pharmacy

* = Indicative figures for total EU market

Items in grey are not mandated by FMD

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