The EU Falsified Medicines Directive
3 weeks to go

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FMD fundamentals

- The EU Falsified Medicine Directive comes into force on 9/2/2019
- It requires you to check the safety features of prescription only medicines (plus pharmacy Omeprazole)
- The checks need to be performed by an electronic system as it links to a database
- The background to FMD was covered in an earlier webinar listed on https://www.npa.co.uk/fmd
Safety Features

tamper evident seal + Unique identifier

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 140531
S/N: 12345AZRQF1234567890
Pharmacy Workflow

FMD says that you need to check the safety features and decommission the unique identifier at the time of supply to the public. There is some leeway as described in The Way Forward document (link on https://www.npa.co.uk/fmd)

You may choose to verify the safety features when the packs enter the pharmacy. You may choose to verify and safety features during or soon after assembly. Before supply to the public, you must have checked the anti-tamper device AND have decommissioned the unique identifier (using an electronic system).

You can reverse the decommissioning to put uncollected items back in stock in most cases, but only within 10 days.

Many will verify-scan at assembly and use that data for an aggregate barcode on the bag which will be scanned to decommission all the bag contents at handover to the patient.
FMD-capable PMR system?

- likely to use aggregate codes on bags to ease decommissioning
- Maintains relationship with PMR providers; no extra supplier
- Could offer accuracy check back to the prescription, either now or at a later date

BUT

- may be more expensive or require a long contract
- Could necessitate alterations to medicine assembly processes
- might need more PMR terminals

https://fmdsource.co.uk/suppliers/ has a list of suppliers
Standalone FMD?

Standalone FMD
• May be less expensive
• May affect the assembly process is less.

BUT
• probably requires extra power sockets and network connections
• unlikely to provide an accuracy checks back to the prescription
• May introduce another IT supplier into the pharmacy
• Additional costs might be incurred later if moving from standalone back to an FMD-capable PMR.

https://fmdsource.co.uk/suppliers/ has a list of suppliers
Careful procurement

Check the system does what you need, but also use this contract checklist from Choosing a PMR system on https://www.npa.co.uk/fmd:

1. What is the contract length?
2. Does it include the PMR, hardware, external network (N3/HSCN), and helpdesk/maintenance/support?
3. Don’t be bounced into signing the contract
4. Read the contract in detail (including small print)
5. Look for tie-in clauses: what opportunities could you miss by being bound to the contract for that long? What are the penalties for either party exiting the contract early?
6. Look for break clauses: does the contract give you sufficient assurance of service continuity?
7. If there are any agreed verbal changes to the contract, make sure that are written onto the contract
8. Watch out for roll-over terms. Make a diary note of the key dates contained in the contract
9. Contact the NPA Legal team if you have any queries about contracts with suppliers at legalindemnityenquiries@npa.co.uk
End user registration

• When you know which system you are going to be using, you will be able to do the end-user registration with www.SecurMed.org.uk

• Registration can take 15 days. Your system supplier may be able to help you.

• If you have a wholesale license as well as being a community pharmacy, you need to register twice!
SOPs

Update your SOPs to include FMD.

See

- [www.npa.co.uk/essential-sops-fmd-versions](http://www.npa.co.uk/essential-sops-fmd-versions)
- [https://fmdsource.co.uk/resources/eu-fmd-scanning-and-error-messages/](https://fmdsource.co.uk/resources/eu-fmd-scanning-and-error-messages/)
Go live

Go live is on 9/2/2019

It’s going to be a slow ramp up

Old stock can still be traded and dispensed until it expires.

Manufacturers get six months’ leeway after registering their new FMD pack artwork

It is important to note the error messages reference to on the previous slide
Shall I wait for Brexit?
Q and A

Q1: Will patients have access to see if their medicines are falsified online?

A1: no

Q2: Are there going to be any materials to inform patients?

A2: Hoping that the NHS will be providing some
**Q and A**

Q1: If I go with the FMD-IT standalone solution, what are the Brexit terms?

A: The supplier tells me:

- The payment of £75 is a non-refundable deposit
- Hardware is purchased and belongs to the client
- "essentially, in the event of NO EU or UK workable FMD system, the contract for the license and support fee (of £25 per month) is cancelled with immediate effect once terminated in writing.

See [https://www.npa.co.uk/fmd-it-limited](https://www.npa.co.uk/fmd-it-limited) for the rest of the details

Q2: what is the lead time

A2: 2.5 weeks at present
Vital resources

- https://www.npa.co.uk/FMD
- https://fmdsource.co.uk/resources/the-way-forward-for-fmd-in-community-pharmacy/
- https://www.securmed.org.uk/
Thank you

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