Falsified Medicines Directive Information Guide

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What is FMD?

The Falsified Medicines Directive, or FMD, is a set of legislation passed by the European Union Parliament, it is designed to protect patients by addressing the issue of falsified medicines entering the legitimate medicines supply chain within Europe.

What is a falsified medicine?

A medicine which may contain little or no active ingredients, the wrong active ingredients, fake or tampered packaging or can be products and / or packaging which have been stolen for re-use or re-sale.

What medicines are included in FMD?

All prescription only medicines (POM's), and a small number of over-the-counter products.

When does FMD start?

The regulation takes effect from 9th February 2019.

What are the safety features?

There are two safety features:

A unique identifier in the form of a 2D data matrix barcode with a human readable feature and an anti-tamper device.

The unique identifier will allow verification of the medicinal product throughout the supply chain, from manufacturing to dispensing to a patient and the anti-tamper device will indicate whether the pack has been opened.

The unique identifier will carry what information?

- Product code
- Serial number
- National reimbursement number *(in certain EU countries)*
- Batch number
- Expiry date

Will Accord be following FMD guidelines?

Yes, all European pharmaceutical manufacturers and imported medicines are required to be adhering to FMD by February 2019.

Is FMD related to Brexit?

No, the introduction of FMD would have taken place regardless of the referendum vote.

Will FMD slow down the supply of medicines in the UK?

Accord has worked hard as a global company to ensure we are ready for FMD and that its introduction will not slow down the supply of medicines in the UK. Working closely with our supply chain has also been key to ensure its smooth transition.

I have one pack with a code and one without, are they still the same?

As long as the Marketing Authorisation numbers (starting with PL, PA or EU) are the same on both packs then the product will be the same.

Is it just the carton that has changed or have the tablets changed too?

It is just the carton that has changed, no change has been made to the medicine inside.

As long as the Marketing Authorisation numbers (starting with PL, PA or EU) are the same on both packs then the product will be the same.

Will all products in the Accord price list display the unique identifier and anti-tamper device from 9th February 2019?

No.

A few products in FMD compliant packs are already being sold but for the vast majority of sales there will be a gradual phase in of FMD compliant packs over the coming months. However, for some products it may take over a year to see FMD compliant product depending on current stock levels. There is no obligation to rework non-compliant stock into compliant stock if it was released for sale prior to the 9th February.

We can confirm that all product released for sale post the 9th February 2019 will comply with FMD and / or any local temporary exemptions.

For more information of specific products please contact the Accord Med Info Team:
medinfo@accord-healthcare.com or 01271 385257

What will happen to product with no serialisation after 9th February 2019, can it still be dispensed?

Yes, any product that was batch released before 9th February can be dispensed without serialisation.

Can stock be returned to wholesalers?

In general, as long as the stock has not been decommissioned and the anti-tamper device is still intact, the wholesalers returns process will be valid although usual Terms and Conditions will apply.

Once FMD is implemented, can we still ring-fence the UK / EU samples and how does the process work with respect to decommissioning?

Once a sample order is placed, stock is then allocated to the order and this "ring fences" the stock for MENA. This process will not change.

Only at the point of picking the stock in preparation for dispatch will the decommissioning be completed.

What is the alert handling process if the UK hub detects a potential falsified medicine?

When scanned the system will verfiy the pack or issue an alert. The system will then send alerts to the National Medicines Verification System, the National Competent Authorities and the EU hub. The EU hub will then alert the manufacturer or parallel distributor.

For more information on what to do in this situation please refer to the links in the RESOURCES AND FURTHER READING section.

European Commission – Medicinal Products

https:/ec.europa.eu/health/human-use/falsified_medicines_en

ABPI The Association of the British Pharmaceutical Industry

www.abpi.org.uk/what-we-do/working-with-government-and-parliament/falsified-medicines-directive-fmd

BGMA British Generics Manufacturing Association

www.britishgenerics.co.uk/key-issues

NPA National Pharmacy Association

www.npa.co.uk/fmd

PSNC Pharmaceutical Services Negotiating Committee

https://psnc.org.uk/contract-it/pharmacy-regulation/falsified-medicines-directive

UK FMD Working Group for Community Pharmacy

https://fmdsource.co.uk

European Medicines Verification Organisation:

www.emvo-medicines.eu