Medicines & Healthcare products Regulatory Agency

Q&A: Disapplication of EU Falsified Medicines Directive safety features in Northern Ireland following agreement of the Windsor Framework

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This information is designed to address common queries on the disapplication of the EU Falsified Medicines Directive (FMD) safety features in Northern Ireland under the Windsor Framework and section 3.2 of guidance for wholesalers and manufacturers.

As of 1 January 2025, UK medicines will no longer display features included for the purposes of compliance with FMD. 2D barcodes and serial numbers remain permitted but must not be recognised by the European repositories system and any such code present would need to be fully removed or covered. Anti-tamper packaging continues to be encouraged.

Contents

Serialisation / 2D Barcodes

1. **Do MAHs need to leave the serialisation space empty, as after 1 January 2025 serialisation is not required in UK?**

   The MHRA continues to allow non-FMD compliant features within this space, or this may be removed entirely.

2. **In accordance with Windsor Framework requirements, can FMD serialisation data continue to be used on new prescription-only medicines (POM) packs provided that the data is not uploaded to the EU hub?**

   MA holders may choose to apply the following features on UK packaging, although this is not compulsory:

   - a 2D barcode (Data Matrix), which may encode data including information about the specific medicinal product, the expiry date, batch number, Global Trade Item Number, and serial number if applicable; and
   - a serial number of any format.

3. **Can packs be EU FMD serialised beyond 31 December 2024 as the UK's verification system was shut down so the serial numbers will never be recognised?**

   If the 2D code is not recognised by the EU repositories system then it is not an FMD compliant feature and is permissible.

4. **Is there a need to apply a 2D code only for batch number and expiry date?**

   The use of 2D barcode is the choice of MAH.

5. **What happens if the carton bears 'UK Only' but has FMD features, including 2D barcode and human readable information?**

   Only cartons with FMD features readable by an NMVO repository require covering. Non-recognisable codes are not FMD features and require no action.

European Medicines Verification System (EMVS) and National Medicines Verification System (NMVS)

6. **What does recognisable means? Is the cessation of uploading the UPI to the EMVS considered as being not recognisable for existing products?**

   Yes, for products released after 1 January 2025.

7. **Can packs released before 1 January 2025 continue to have the 2D barcodes recognised by the EU repository system?**

   Batches QP certified prior to 1 January 2025 may remain on the market. The data will no longer be held on a UK repository.

8. **Is it permissible to release a product with the FMD human-readable information printed on the carton, while not uploading this information to the EU Hub, and without covering or removing the FMD human-readable details?**

   This is acceptable providing that the data is not recognised, i.e., it has not been uploaded to the EU Hub (European Medicines Verification Organisation (EMVO)).

9. **Is it acceptable to leave the 2D barcode uncovered on packs certified in 2025 but produced in 2024, considering that the NMVS disconnection will render the serialisation details unrecognisable?**

   Yes, providing that the data is not recognisable as FMD code i.e. it has not been uploaded to EMVO.

10. **Will UK companies have direct access to the EMVO FMD system from 1 January 2025 once SecurMed is no longer operational?**

    No, please refer to the EMVO website for details.

11. **Is it acceptable for an MAH to have a 2D barcode based on GS1 codings that is not uploaded to the EU repositories system and therefore not recognised by it?**

    The continued use of 2D barcodes is acceptable provided these are not for EU FMD purposes.

12. **Can EU licensed medicines imported into the UK as unlicensed products or supplied to the UK under labelling exemptions have their FMD 2D barcode uploaded to the EU Hub?**

    It is a requirement for authorised EU medicines to be uploaded into EMVO. These should be decommissioned to allow for export i.e. to UK.

13. **Does the MAH need to remove the serial number from secondary packaging completely, or is printing a serial number on a carton acceptable if it has not been uploaded to the EU Hub or not recognized by the EMVS?**

    Only active codes on another repository require removal.

14. **Is it acceptable for an MAH to continue uploading EU-compliant 2D barcodes to EMVO after 31 December 2024 for UK products?**

    No. Uploads to EMVO for UK products should cease to comply with the Windsor Framework.

15. **Why do EU 2D compliant barcodes need to be covered up or removed from packs after 31 December 2024, when the NMVS would have been disconnected from the EMVS?**

    Existing inventory released prior to 1 January 2025 does not require 2D codes to be covered. Only 2D FMD compliant codes released after 1 January 2025 require covering.

16. **If the link to the EU hub is severed for the UK by EMVO from 1 January 2025 then doesn't this resolve any potential non-compliance concerns from the outset?**

    Provisions remain to cover contingency measures, such as goods uploaded to other repositories in error.

17. **If the SecurMed system is disconnected from EMVO as of 1 January 2025 and the MAH is not uploading any codes, does the 2D barcode need to be removed or covered?**

    No action is required for codes not being utilised for EU FMD purposes.

FMD decommissioning

18. **From 1 January 2025 does legacy serialisation data on EMVS need to be decommissioned?**

    No.

19. **For old packaging in the UK that was uploaded to EMVO, does it need to be decommissioned from 1 January 2025 to continue distribution?**

    No.

20. **If the QR code on the incoming pack has been FMD decommissioned, could it remain visible?**

    The MHRA understands that any stock exported from the EEA should be decommissioned prior to supply. EEA livery medicine imported to the UK as unlicensed medicine do not require the 2D barcode to be covered. EEA livery medicine imported to the UK for parallel import (PLPI) purposes do require the 2D barcode to be covered.

Use of unique identifiers

21. **Would tamper evident labels need to be applied if tamper evident caps or seals are used?**

    The MHRA continues to encourage the use of tamper evident measures. This decision is made by individual organisations.

22. **Does a label need to be anti-tamper if this needs to be applied?**

    'UK Only' labels must be secure and permanent, as detailed in our labelling and packaging guidance. The MHRA encourages the retention of tamper evidence seals.

Distance Selling Logo Scheme

23. **Does the disapplication of FMD include the disbanding of the Distance Selling Logo Scheme in Northern Ireland?**

    No, the Windsor Framework makes no changes to the Distance Selling Logo scheme. Pharmacies in Northern Ireland should continue as they currently do. Pharmacies in Northern Ireland who wish to sell P-medicines and/or dispense POMs online will still be required to continue to register for the Distance Selling Logo with the MHRA after the 1 January 2025 and display the logo on their webpage.

General

24. **After 1 January 2025, how will alerts be monitored? Will there be an MHRA repository monitoring alerts system since there will be no uploads to the NMVS?**

    Following the disapplication of the EU Falsified Medicines Directive (FMD) safety feature requirements, there will be no serialisation in the UK. FMD alerts are dependent on reporting by companies, and organisations are required to remain vigilant to the risk of falsification. The MHRA will respond to queries form EU competent authorities.

25. **Will the MHRA keep their FMD web page up to date, given that Italy and Greece will no longer be under FMD regulation derogation from 1 January 2025?**

    All pages featuring regulatory guidance will be updated as and when required.

26. **Can a PL MA be released and distributed without FMD requirements before 31 December 2024 once a 'UK Only' label has been implemented?**

    Please refer to section 7 (supply of existing stock in existing packs) of our labelling and packaging guidance.

27. **Can packs produced in compliance with FMD requirements prior to the end of 2024, continue to be certified in 2025 without further action?**

    No, QP certification after 31 December 2024 is for 'UK Only' labelled materials, when FMD has been disapplied.

Contact information

- For any enquiries about FMD and the Safety Features not covered by published guidance, please email fmd.safetyfeatures@mhra.gov.uk
- If you are a manufacturer and have a query regarding the compliance of your packaging, or any other FMD GMP specific question, please email FMD.GMPenquiries@mhra.gov.uk
- For any GDP FMD enquiries, please email the GDP inspectorate at gdp.inspectorate@mhra.gov.uk
- For anything else, please email the MHRA Customer Services Centre at info@mhra.gov.uk or telephone 020 3080 6000
- Visit our MHRA Windsor Framework Hub for further information and resources on the Windsor Framework agreement on supply of medicines in Northern Ireland