Northern Ireland Exit from the EMVS (NIXIT)

Questions and Answers (Q&A) – Version 4.0

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The answers may include recommendations or advice. You are solely and exclusively responsible for deciding any particular course of action or omission and for implementing any actions or taking any decision on this basis. EMVO disclaims all liability with regard to such actions or decisions and their consequences.

This document sets out the main questions with regard to NIXIT together with EMVO's recommendations **targeting the OBPs**. The document shall be updated in case further questions/information come to EMVO's attention.

Regularly consult EMVO's website and Knowledge Database (here) to follow up on the latest communication.

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1. What is the legal basis for the exit of UKNI from the EMVS?

Answer: The Protocol on Ireland/Northern Ireland, known as the Windsor Framework, is part of the agreement that set out how the United Kingdom would leave the European Union. This agreement became effective on February 1, 2020.

The Northern Ireland Protocol (NIP) stated that EU pharmaceutical laws would apply to Northern Ireland only, starting from January 1, 2021. However, this will change when the Windsor Framework comes into effect to alter the terms of the NIP.

The Windsor Framework established long-term plans for supplying medicines to Northern Ireland. It ensures that medicines can be approved and licensed across the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), following UK rules and authorization procedures only. Additionally, the Windsor Framework mandates in Article 36 that EU Falsified Medicines Directive (FMD) requirements won't apply to medicines sold in Northern Ireland.

Ultimately, the FMD rules will no longer apply in Northern Ireland once the provisions set by Regulation (EU) 2023/1182 are applied, as outlined in Article 14 of that Regulation.

2. When does the Regulation (EU) 2023/1182 (Windsor Framework) become applicable?

Answer: Regulation (EU) 2023/1182 entered into force on 21 June 2023 *(the day following that of its publication in the Official Journal of the European Union)* and it should apply from 1 January 2025 as confirmed by the Notice published by the European Commission in the Official Journal of the European Union.

3. What is the consequence for medicine packs aiming to be distributed in UKNI as of 1 January 2025?

Answer: Following the application of Regulation (EU) 2023/1182 from 1 January 2025, FMD will be disapplied on packs intended to be supplied in UKNI.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on the labelling and packaging of medicinal products for human use following agreement of the Windsor Framework which describes the circumstances in which 2D barcodes and anti-tampering devices may continue to be applied to packs intended for sale in the UK[1] after the FMD disapplication date.

4. What will happen to the UKNI Medicines Verification System after 31 December 2024, should the Regulation (EU) 2023/11821 enter into force on 1 January 2025?

Answer: The UKNI Medicines Verification System will be closed down resulting in the termination of its connection to the EMVS. Hence, all data previously stored in the UKNI MVS will be permanently erased, with no further access possible.

5. Are there any new technical requirements or specifications that we need to adhere to in order to maintain connectivity with the EU Hub?

Answer: No.

6. Are there new data exchange protocols or encoding standards that need to be implemented?

Answer: No, there are no new data exchange protocols or encoding standards that need to be implemented.

7. Will there be any changes in data formats or standards required for transmitting data to and from the EU Hub system post disconnection of the UKNI?

Answer: Although the process of uploading the Product Master Data (PMD) or Product Pack Data (PPD) will remain unchanged, some changes will be needed since selecting "GB" as a market after 1 January 2025, whether for single or multi-market purposes, will always result in errors.

8. How will the OBPs' existing data in the EU Hub which includes the target market "GB" be affected by these changes?

Answer: The PMD of multi-market products uploaded before 1 January 2025 must be updated by removing the market "GB" from the designated markets. You can remove the "GB" market

[1] Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK (www.gov.uk)

by updating the last version of the affected PMD. No action is required for the PMD of single-market products.

9. How are error responses standardized, and what response codes are used to communicate different types of errors or exceptions?

Answer: The main #A codes that are going to be used are "#A16 - Data Validation error", "#A18 – Disconnected Market GB" and "#A22 - Market not found". The next few questions provide further information.

10. When should an OBP update the Product Master Data (PMD) which has the market "GB" as one of the designated markets?

Answer: The OBP **must** update the PMD of multi-market products by removing the market "GB" from the designated markets as of 1 January 2025.

As soon as the Regulation is applicable, the upload of the PMD with the market "GB" listed as one of the designated markets will not be possible.

Consequently, the EU Hub will respond with an A-16 **data validation error (#A16)** followed by an A-22 **"Market not found" (#A22) error**. The request will fail and you will be required to remove the market "GB" before proceeding further with the data upload for other markets.

11. Can an OBP upload "GB" single market pack data after 31 December 2024?

Answer: No, the UKNI National system will be disconnected as of 1 January, 2025 providing that the conditions mentioned in question number 2 are met by the UK government. Therefore, OBPs will be unable to upload GB single-market packs after this date.

When an OBP tries to upload GB single-market packs after 31 December 2024, the EU Hub will send an error message to inform the OBP that the upload is not possible.

For a PPD ("GB" only) request, the Hub will respond with a "#A16 - Data Validation error". Additionally, an "#A22 - Market not found" will be added to the response.

12. Can OBPs upload multi-market packs with the "GB" as one of the designated markets after 31 December, 2024?

Answer: Multi-market packs between UKNI and an EU/EEA Member State(s) will no longer be possible after the Windsor Framework takes effect for medicines. Therefore, as of 1 January, 2025 or following the entry into force of Regulation (EU) 2023/1182, OBPs will

receive error code(s) from the EU Hub should they try to upload multi-market packs which have the "GB" as a market.

Therefore, for a Product Pack Data (PPD) (multi-market that includes the "GB" market) request, the Hub will only record an audit event "#A22 - Market not found" and mark the transaction as '**SUCCESS'** for the other markets. The OBP will receive the message '**SUCCESS'** including the error code #A18 with the message "Disconnected Market GB". The process of uploading the PMD from the OBP side will **NOT CHANGE.**

13. What will happen to packs uploaded before 1 January 2025?

Answer: Article 12 of the Regulation (EU) 2023/1182 states that "*Medicinal products that have been lawfully placed on the market in Northern Ireland before the date of application referred to in Article 14, and that are not repackaged or relabelled after that date, may be further made available on the market in Northern Ireland until their expiry date without being required to comply with the specific rules laid down in Articles 3, 4 and 5*."

NOTE: We strongly recommend that OBPs **DO NOT UPLOAD** any packs on the 31 of December 2024 as the cut-off point will be at 23h00 GMT on 31 December 2024, should Regulation (EU) 2023/1182 enter into force on 1 January 2025.

14. How will Product Master Data of single-market GB products be amended on EU-Hub after 1 January 2025? Will it be automatically removed from EU-Hub and OBPs are required to amend only multi-market products with exclusion of GB?

Answer: Single-market – the PMD uploaded before 1 January 2025 will remain unchanged in the EU Hub. No actions required from your side.

Multi-market – as answered under Q8, the PMD uploaded before 1 January 2025 must be updated by removing the market "GB" from the designated markets. You can remove the "GB" market by updating the last version of the affected PMD.

15. What should be the status of the pack in the EMVS of an EU/EEA pack supplied to the UKNI market?

Answer: After 1 January 2025, EU/EEA packs intended to be placed into the market in Northern Ireland are to be decommissioned by the selling entity to the status "Exported"* in the EMVS when the packs leave the EU/EEA. This status can be reverted up to 10 days, if needed.

The derogation[2] currently in place from the requirement to decommission from export UK single market packs or joint UK packs with Ireland, Malta or Cyprus being sent to the UK will expire on 31 December 2024.

16. Should EU/EEA packs intended for EU/EEA markets that are supplied through wholesalers in Northern Ireland be decommissioned?

Answer: EEA authorised packs intended for the EEA market that are supplied via wholesalers in Northern Ireland, should not be decommissioned prior to being sent to Northern Ireland.

17. Which transactions and reports will be affected by NIXIT?

- **PMD GB Single Market:** If a Product Master Data (PMD) request targets only the GB market, the system shall respond with a **data validation error (#A16)** indicating **"Market not found" (#A22),** resulting in a failed request.
- **PMD Multi-Market:** Similarly, if GB is among the target markets but not the only one in a PMD request, the system shall respond with the same error as a PMD GB Single Market and fail the request.
- **PPD Single Market:** For a Product Pack Data (PPD) request targeting only the GB market, the system shall record a market not found audit event **"Market not found" (#A22)**, respond with a data validation error **data validation error (#A16)**, and fail the request.
- **PPD Multi-Market:** If GB is among the target markets but not the only one in a PPD request, the system shall record the audit event, distribute the request to non-GB markets, and respond with a success message including an error code **(#A18) indicating "Disconnected Market GB".**
- **PSUM Single Market:** In a Pack State Update (PSUM) request targeting only GB, the system shall record the audit event, respond with a **"Market not found" (#A22)** error, and fail the request.
- **PSUM Multi-Market:** If GB is among the target markets but not the only one in a PSUM request, the system shall record a market not found audit event **"Market not found" (#A22)**, distribute the request to non-GB markets, and respond with a success message.
- In a **Recall Batch (RCB)** request targeting GB, the system shall record a market not found audit event **"Market not found" (#A22)**, respond with a confirmation message, distribute the request to non-GB markets, and respond with a confirmation message indicating the market not found error for GB.

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[2] Final paragraph of Article 22 of Commission Delegated Regulation on Safety Features (EU) 2016/161 as inserted by Commission Delegated Regulation (EU) 2022/315

*Please note that the status "Exported" only refers to the status available in the EMVS and is not related to any other process or pharmaceutical regulation.

- For a **Verify Bulk of Packs (VBOP)** request targeting GB exclusively or where GB was the only successful distribution, the system shall respond with a market not found error and fail the request. - If GB is among the target markets but not the only one in a VBOP request and at least one non-GB market has successfully received packs, the system shall distribute the request to those markets and respond with success.
- In a **Product Withdrawal (WDP)** request targeting GB, the system shall record a market not found audit event **"Market not found" (#A22)**, respond with a confirmation message, distribute the request to non-GB markets, and respond with a confirmation message indicating the market not found error for GB.
- For **Report (RPT) requests**, if a **Batch Recall, Pack Disclosure, Packs by Status, Packs Status by Batch, or Withdrawn Product report** includes GB market records, no request shall be sent to the GB national system. The system shall display a market not found **(#A22)** error for GB in the section detailing errors received from national systems.

18. Are there any test environments available for us to conduct our own testing and validation processes?

Answer: On 17 September 2024, the UKNI market will be disconnected from the EU HUB IQE Environment enabling OBPs to validate their processes ahead of the close down of the UKNI Medicines Verification System and its disconnection from the EU HUB PRD Environment.

Please mind that due to planned technical testing (IOTs), the EU HUB IQE will be with limited availability on the following:

- From 9 to 17 September 2024 (including)
- From 14 to 22 October 2024 (including)
- From 18 to 26 November 2024 (including)

19. How will the updated EU Hub system integrate with our existing IT infrastructure and systems?

Answer: The updated EU Hub system will seamlessly integrate with your existing IT infrastructure and systems, requiring no updates or adjustments for compatibility. However, for OBPs utilizing direct connections and implementing personalized processes, we recommend consulting with your internal IT team to ensure a smooth integration process.

20. How will the updated EU Hub system handle increased volumes of data and transactions, particularly during peak periods?

Answer: The EU Hub system is already robust enough to handle increased volumes of data and transactions, even during peak periods. Additionally, we have contingency plans in place to mitigate any potential overloading of the EU Hub, ensuring uninterrupted operation and efficiency.

21. What provisions are in place for disaster recovery and redundancy to minimize the risk of data loss or system downtime?

Answer: As previously mentioned, we have robust contingency plans in place to mitigate any potential risks, including those related to disaster recovery and redundancy.

22. Are there mechanisms in place to ensure backward compatibility with older schema versions while accommodating changes required by UKNI related regulations?

Answer: As it currently stands, the EU Hub schema version is not going to be modified or changed as part of this implementation. Therefore, OBPs should not be concerned about potential changes to their systems or backward compatibility issues.

23. What third-party service providers for us as the OBPs or dependencies are critical for the operation of the EU Hub system, and how will UKNI disconnection impact these relationships?

Answer: As previously stated, the EU Hub system will seamlessly integrate with your existing IT infrastructure and systems without requiring any updates or adjustments for compatibility. Nevertheless, OBPs using direct connections and personalized processes should collaborate with their internal IT teams to ensure a smooth integration process.

24. Are there any changes to existing APIs or the introduction of new ones with the update?

Answer: No changes to the existing APIs are currently foreseen due to NIXIT. However, please be reminded that other changes related to the PMD and PPD update, namely the introduction of the new mandatory fields, are being prepared and will soon be communicated to the OBPs.

25. Are there new endpoints introduced or existing endpoints deprecated as a result of regulatory changes or system updates?

Answer: No, there are no new endpoints introduced or existing endpoints deprecated as a result of regulatory changes or system updates. Endpoints remain untouched and unchanged, as they are out of scope for this implementation.

26. Can a UK pharmaceutical company act as an OBP for non-UK MAHs after 31 December 2024, should the Regulation (EU) 2023/11821 enter into force on 1 January 2025?

Answer: Yes, a UK pharmaceutical company can act as an OBP for non-UK MAHs as long as *Appendix 4 – Addendum only applicable to non-EEA OBPs* from the Participation Agreement (PA) is signed.

27. What are UKNI legacy packs?

Answer: Legacy packs are batches of medicinal products for human use which have been lawfully placed on the market in Northern Ireland before the Regulation (EU) 2023/1182 becomes applicable and are not repackaged or relabelled after that date.

28. What will happen if end-users (pharmacies, wholesalers, etc) in EU/EEA countries need to verify/(undo) decommission UKNI single market legacy packs in their possession after 1 January, 2025?

Answer: If an end-user tries to perform one of the above mentioned actions, the EMVS will respond with a message notifying the end-user that the UKNI system no longer exists.

29. Will there be any training or support provided to help us adapt to these changes?

Answer: Yes, EMVO will organise several live workshops/webinars to help you adapt to the changes. The exact dates will be communicated soon.

30. Are there resources available to assist with troubleshooting or addressing any issues that may arise during the transition period?

Answer: EMVO is currently updating the Master Data Guide which will reflect the matter and provide useful tips on how to adapt as quickly and effectively as possible. Moreover, you are always invited to contact the Helpdesk (helpdesk@emvo-medicines.eu) should you require an immediate assistance.

31. How will you communicate updates and provide ongoing support regarding these changes?

Answer: EMVO will communicate all updates via Letters of Announcements. We remind you that only the SPOC/SPOC Assistants receive them so please keep their contact details always up to date. You can do this via your OBP Portal in step 5 Maintenance. Moreover, we invite you to regularly consult our website which contains the latest communication and updates under the "Knowledge Database" tab.

32. Are there designated points of contact or channels through which we can seek assistance or clarification?

Answer: We recommend you seek immediate assistant at EMVO's Helpdesk (helpdesk@emvo-medicines.eu). Our colleagues will address your questions at their earliest availability. Alternatively, you can also call us at +32 2 657 00 08.

External references:

- **European Medicines Agency:**
  - Questions and answers to Stakeholders on the implications of Regulation (EU) 2023/1182 for centrally authorised medicinal products for human use: https://www.ema.europa.eu/en/documents/other/questions-and-answers-stakeholders-implications-regulation-eu-2023-1182-centrally-authorised-medicinal-products-human-use_en.pdf

- **European Union regulation:**
  - REGULATION (EU) 2023/1182 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC:
  - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R1182

- **European Commission guidance:**
  - EU-UK relations: EU takes further steps to implement the Windsor Framework: https://www.consilium.europa.eu/en/press/press-releases/2023/05/30/eu-uk-relations-eu-takes-further-steps-to-implement-he-windsor-framework/
  - Questions and Answers: political agreement in principle on the Windsor Framework, a new way forward for the Protocol on Ireland / Northern Ireland: https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_1271
  - REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the assessment of written guarantees provided by the United Kingdom to the Commission pursuing Article 8 of Regulation (EU) 2023/1182 of the European Parliament and of the Council on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=COM:2024:565:FIN
  - Notice in accordance with Article 14 of Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC concerning the date from which the Regulation applies: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202407473

- **UK guidance:**
  - Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework: https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework
  - Q&A on Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework: https://mhra-gov.filecamp.com/s/i/Windsor_Framework_Labelling_QA

- The MHRA issues final call to comply with Windsor Framework arrangements for medicines from January 2025: https://www.gov.uk/government/news/the-mhra-issues-final-call-to-comply-with-windsor-framework-arrangements-for-medicines-from-january-2025
- Guidance – Wholesalers & manufacturers guidance following agreement of the Windsor Framework: https://www.gov.uk/government/publications/wholesalers-manufacturers-guidance-following-agreement-of-the-windsor-framework/wholesalers-manufacturers-guidance-following-agreement-of-the-windsor-framework
- Northern Ireland Department of Health: Windsor Framework - Summary and Frequently Asked Questions: https://www.health-ni.gov.uk/articles/windsor-framework-summary-and-frequently-asked-questions

- **Irish guidance:**
  - Brexit and the Regulation of Health Products – Latest Information: https://www.hpra.ie/homepage/about-us/stakeholders/brexit/brexit---latest-information
  - Questions and answers on the Windsor Framework: https://www.hpra.ie/homepage/medicines/news-events/item?t=/questions-and-answers-on-the-windsor-framework&id=3e3b1526-9782-6eee-9b55-ff00008c97d0