Medicines & Healthcare products Regulatory Agency

Q&A: Wholesalers and manufacturers requirements following agreement of the Windsor Framework

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This information is designed to address common queries about guidance for wholesalers and manufacturers in relation to medicinal products for human use under the Windsor Framework.

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Qualified Person (QP) obligations and batch release (QP certification)

1. **Will a QP in Northern Ireland be able to certify batches destined for EU?**

   Medicinal products not intended to be placed on the Northern Ireland market can continue to be wholesaled, manufactured and batch released from Northern Ireland to the EU. For further information, please see section 3.5 of our Wholesalers and Manufacturers guidance following agreement of the Windsor Framework.

2. **For batches released before 31 December 2024, does a QP have to re-certify (generate a new CofC) with the UK listed in place of GB after 1 January 2025?**

   Any stock in existing packaging already QP certified and placed on the market (in Great Britain and Northern Ireland) can continue to be supplied to patients in the relevant territory until the date of expiry. For further information, please see section 3.6 of our Wholesalers and Manufacturers guidance following agreement of the Windsor Framework.

3. **What is the QP permanent residence location requirement for QPs named in a UK MIA who conduct QP certification for UK market or exportation from UK?**

   There is no change to the existing requirement that to be named on a UK Manufacturing Authorisation the QP must be based in the UK. For further information, please see section 3.7 of our Wholesalers and Manufacturers guidance following agreement of the Windsor Framework.

4. **Post 1 January 2025, if products with older labels are in the Marketing Authorisation Holder's (MAH) warehouse but QP released and unsold, do they require an additional 'UK Only' label?**

   No. For further information, please see section 3.1.3 of our Wholesalers and Manufacturers guidance following agreement of the Windsor Framework.

5. **Can we receive batches without 'UK Only' which have legitimately been QP certified prior to 1 January 2025, but delivered to our 3PL after 1 January 2025?**

   Yes. For further information, please see section 3.6 of our Wholesalers and Manufacturers guidance following agreement of the Windsor Framework.

6. **Are medicines, released by a QP/RPi in a UK warehouse without a 'UK Only' label but not sold and reaching pharmacies until January/February 2025 considered on the market?**

   Batches that are QP Certified before the implementation date of the Windsor Framework can continue to be supplied.

Responsible Person for Import (RPi) obligations

7. **Is an RPi check required for Northern Ireland?**

   The movement of medicines from EU to Northern Ireland is not considered export from the EU and an RPi is not required.

8. **Does stock without a ‘UK Only’ label need to be RPi released before the 1 January 2025 (in the UK) or can it be QP released pending RPi release (in the EU)?**

   Stock without ‘UK Only’ must be QP released, however, does not require RPi release prior to Windsor Framework implementation.

9. **What would be a practical way for the RPi to demonstrate compliance of the packs with the Windsor Framework if the released batch cannot be physically examined upon delivery?**

   The MHRA does not proscribe methods utilised to assess compliance of goods. It is the responsibility of the RPi to assess that packs are compliant with the Windsor Framework by mechanisms they deem to best demonstrate that goods have been QP Certified according to the conditions of the Marketing Authorisation. The RPi process should encompass the physical receipt and assessment of inventory.

10. **What are the expectations for RPi checks (MA holder) and evidencing that a pack is not recognised by the EU repositories system?**

    For UK operators, there is no NMVO and therefore no expectation that an RPi can verify a pack is not recognised. The MAH should satisfy themselves that goods released to the UK will be compliant with the conditions of the Marketing Authorisation and Windsor Framework.

11. **Is there a requirement for an RPi to complete pre and post import approval for import of radioactive hot products like is required for importation of cold kits?**

    The RPi must complete all checks for all products. We recognise some products, such as radiopharmaceuticals, present a challenging supply chain for physical verification. Should you seek to import medicines with a particularly short shelf life, please contact the GDP Inspectorate (GDP.Inspectorate@mhra.gov.uk) for further discussion.

12. **How are UK RPi's supposed to make sure that the ‘UK Only’ is displayed on packs, post QP release?**

    An RPi is required to ensure goods have been QP certified. This requirement has not changed.

13. **For products requiring RPi checks, is it the QP release date or the RPi check/approval that determines the date a product is placed on the market?**

    For the purposes of Windsor Framework compliance, the date a product is considered to be placed on the market is based on the date of the QP certification.

14. **Is an RPi required for veterinary medicines imported from EU into UK for UK market?**

    Please contact the Veterinary Medicines Directorate for further guidance regarding veterinary medicines import.

15. **Is there is a requirement to conduct an RPi check on products being sent from EU (QP release in EU) direct to Northern Ireland?**

    The current arrangements with regards to the requirements and role of an RPi remain and are not affected by the Windsor Framework. For further information, please see our Sourcing medicines for the UK market guidance.

16. **If stock is shipped from EU to Northern Ireland without RPi oversight, can it the stock freely circulate in GB?**

    Yes. For further information, please see our Sourcing medicines for the UK market guidance.

Import activity

17. **Can a batch that has been EU QP certified before 31 December 2024 without a 'UK Only' label be imported and RPi released in the UK after 31 December 2024?**

    Batches can be released but only supplied to its authorised market.

18. **From January 2025, do all products imported from the EEA for the Parallel Import market need to be decommissioned by the supplying wholesaler? How is this confirmed?**

    Yes, this activity should be detailed within your supplier agreements or other means to provide assurance.

19. **Can medicines be brought into the UK after December 2024 that have been QP released in the EU before the 1 January 2025 and do not have 'UK Only' packaging?**

    Yes, medicines do not need to be imported by the Windsor Framework's 1 January 2025 implementation date.

20. **Can medicinal products be imported directly into the UK under WDA RPi release after QP release from a company located in Spain, and is there a list of approved countries for batch testing and importation of medicines?**

    Yes, medicines can be imported from countries named on a list by WDA(H) holders. A list of these countries can be viewed here: List of approved countries for authorised human medicines - GOV.UK

21. **When is a product considered 'on the market' ? Is this at the point where it is released by a QP for the specific market or when in physical transit?**

    For the purpose of the Windsor Framework, 'UK Only' goods are considered to be 'on the market' once QP certified.

Export activity

22. Can you export products labelled with ‘UK Only’ to the EU from 1 January 2025?

Goods may only be exported to territories or countries where they may be legally supplied. Exporters must satisfy themselves that any goods supplied must be in line with local compliance or legal requirements. For further information, see guidance on UK medicines export and Windsor Framework labelling requirements.

23. Does the ‘UK Only’ label have to be applied to UK packs but not packs that are only for export?

Yes, however, UK MA packs can also be exported provided they are compliant with national and local requirements.

24. What is the situation for packs destined for British Overseas Territories and Crown Dependencies, e.g. Guernsey, Jersey, Gibraltar for UK only on packs?

The Windsor Framework applies to the UK only. Packs may be supplied for export to those territories.

25. Will an export licence be needed if a product with the ‘UK only’ label is sent to an EU site for investigation purposes only?

This question should be directed to the local National Competent Authority.

26. Can products with a Northern Ireland MA (PLNI) be circulated within the UK?

PLNI products may only be supplied in Northern Ireland.

Storage of medicines

27. If a product is QP released in Northern Ireland, is it correct that it cannot go into the EU for centralised storage by a company before being sent to GB for distribution?

From 1 January 2025, it will no longer be possible to utilise EEA located storage facilities to store ‘UK Only’ labelled medicines that have been physically placed on the market in the UK. For example, it will no longer be possible to send goods into the EEA from the UK for storage purposes.

28. If a Contract Manufacturing Organization (CMO) located in Northern Ireland uses sites in EU for storage of finished goods, does this mean that only UK goods that have not been QP released can be stored in EU?

Goods may continue to be stored within the EU up until they are placed on the market.

29. Can products be QP released in EU countries awaiting shipment to the UK before 31 December 2024 and still be received and distributed in the UK after 1 January 2025?

UK label inventories that have been QP certified in the EU and held at a manufacturing site or pre-wholesaler may continue to be stored there until supplied into the UK.

30. **Will the Windsor Framework agreement still allow distributors based in Northern Ireland to hold products not intended for the UK or Northern Ireland market (as referred to in Article 1 (1) of Regulation (EU) 2023/1182) and sell them into the Republic of Ireland, provided that such products are in conformance with EU regulations and are held separately from UK medicines?**

    Sites located in Northern Ireland may continue to be used to store medicines for the UK and EU territories, respectively, however must ensure that medicines must only be supplied to their intended markets. All medicines must comply with the applicable regulations for the intended market.

31. **Is it acceptable for export packs with the 'UK Only' label to be QP certified in the EEA, stored in EEA warehouses, but not be imported into the UK or RPi released to the UK market?**

    Yes, provided they have not entered the UK and are not placed on the market.

32. **Will EU packs for EU consumption but stored in Northern Ireland need to be decommissioned?**

    European Medicines Verification Organisation (EMVO) guidance states that decommissioning is not required for packs prior to being sent to Northern Ireland. For storage, please refer to question 16 of the Northern Ireland Exit from the EMVS (NIXIT) Q&A document.

33. **What are the restrictions on storing 'UK Only' stock in the EEA after QP release, if the warehouse is owned by the MAH?**

    If goods have not been placed on the market they may remain within the EEA.

Supply of stock released before 1 January 2025 in existing packs

34. **If a product is QP released in Northern Ireland, is it correct that it cannot go into the EU for centralised storage by a company before being sent to GB for distribution?**

    From 1 January 2025, it will no longer be possible to utilise EEA located storage facilities to store 'UK Only' labelled medicines that have been physically placed on the market in the UK. For example, it will no longer be possible to send goods into the EEA from the UK for storage purposes.

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40. **What are the restrictions on storing 'UK Only' stock in the EEA after QP release, if the warehouse is owned by the MAH?**

    If goods have not been placed on the market they may remain within the EEA.

41. **Can joint EU/ GB stock QP released into the UK market before 1 January 2025, be supplied into NI and GB and be fully available post 1 January 2025?**

    Yes, joint EU/ GB stock can continue to be supplied to the UK market until the expiry date.

Packs released with the 'UK Only' label before 1 January 2025

42. **Does stock for Northern Ireland need to be physically in the Northern Ireland market or released for the market by 31 December 2024?**

    Goods need to be QP certified by 11pm 31 December 2024 (midnight Central European Time).

43. Can stock QP released in December 2024, be sold into the UK after 1 January 2025 without the 'UK Only' label?

PLGB goods without 'UK Only' may only be sold within Great Britain. They may only be supplied into the Northern Ireland market if on the NIMAR list.

44. Will distributors be able to check if a product has been placed on the market before 1 January 2025 or will this information be available via the manufacturer?

The manufacturer will be able to provide such information.

Stickering

45. If stickering is used, does the 30 June 2025 date refer to the point it can be QP released with a sticker on?

Yes, the application of a 'UK Only' sticker will need to be done prior to certification by a QP which must be done by 30 June 2025.

46. Can stickered 'UK Only' stock remain in circulation after the 6 months (post 30 June 2025)?

Once QP certified these batches may remain in circulation until expiration date.

47. For manufacturing contingency/timings, can stickers be applied by a secondary QP after the primary QP release?

QP certification, for release to market, can only be performed after all manufacturing activity has been performed. Please refer to EU GMP Annex 16.

Decommissioning packs

48. For products QP certified before 1 January 2025, how should the decommission of the packs be performed?

There is no requirement to decommission medicines legally on the market prior.

49. Do wholesalers selling EU centralised authorised procedure (EU CAP) products to Northern Ireland need to stop doing so on 1 January 2025?

EU CAP products QP released after 1 January 2025 are no longer authorised for supply into the NI market, but wholesale activity may continue for supply to EU. Wholesale activity with EU for Northern Ireland based WDA(H) holders is not impacted by the Windsor Framework arrangements.

50. How do you ensure that the batches are decommissioned / physically destroyed after 1 January 2025?

The UK repository will no longer exist and no decommissioning steps are required. Manufacturers and wholesalers should maintain appropriate records of good destruction processes in line with GMDP guidance.

51. Do EU packs that have been imported into the UK from the EEA as an unlicensed medicine or supplied to the UK under labelling exemptions need to be decommissioned prior to import and does the RPi (for GB) need to confirm this?

As the derogation on decommissioning is a matter for the European Medicines Agency and the relevant National Competent Authority, this should be discussed with them. The MHRA understanding is that goods exported to the UK from the EEA should be decommissioned prior to supply. The RPi should seek assurances from their supplier that this has been completed, however, there are no independent UK mechanisms to verify this.

Supplying medicines for clinical trials

52. Does the Windsor Framework have any impact on wholesalers supplying medicines for clinical trials in UK and Europe?

Clinical trials are outside the scope of the Windsor Framework. Batches on the market should meet all relevant legal requirements including those of the Windsor Framework.

53. For clinical trial purposes, will it still be possible to ship EEA sourced commercial products to a packager in Northern Ireland, assuming they have been decommissioned on export?

The Windsor Framework only applies to 'authorised' medicines, so this is acceptable.

54. Can a 'UK Only' labelled pack be supplied into the EU where it is intended to be a comparator in a clinical trial?

You will need to consult with the local National Competent Authority to confirm this.

Contact information

- For any GDP enquiries, please email the GDP inspectorate at gdp.inspectorate@mhra.gov.uk
- For any GMP enquiries, please email GMP inspectorate at gmpinspectorate@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
- For enquiries about veterinary medicines, please contact the Veterinary Medicines Directorate - GOV.UK