Live Webinar with Fusion Pharma
The Windsor Framework - Consolidated Q&A

Q: If a product is QP released without Windsor framework changes in the EU prior to Jan 1st 2025, can we continue to import it in the U.K. after this time?
A: Yes, any stock QP released prior to 1st Jan 2025 can continue to be supplied to the market it was released for, regardless of whether it has been updated or not.

Q: Regarding PLGB licenses on the NIMAR list, my understanding is we can update the labelling now and implement ahead of 1st Jan 2025 and the product can go to Northern Ireland. Is that correct?
A: All PLGB products can be updated with 'UK Only' and released to the GB market prior to 1st Jan 2025. If the product is included on the NIMAR list, this can be distributed to Northern Ireland.

Q: Post Windsor framework implementation: Can a QP releasing in NI release to the EU Market? Will CMDOs operating in UK /NI be able to register Serialisation codes for EU manufacturing?
A: As per HPRA Q+A - As indicated in footnote 45 of the Notice to Stakeholders issued by the European Commission and the European Medicines Agency, batch release by a Qualified person of an importer / manufacturer established in NI is recognised in the EU as per the sixth subparagraph of Article 7(3) of the IE/NI protocol. The same subparagraph also refers to batch testing.

Q: Will PLNIs be specific to NI only and remain as PLNI?
A: Yes, PLNIs will remain as valid licences, however they will only be able to be supplied to Northern Ireland. Please note that from 1st Jan 2025, companies will no longer be able to hold both a PLGB and a PLNI for the same product (this is discussed in the Regulatory webinar).

Q: Does this have impact to the NI protocol?
A: Yes, the Windsor Framework replaces the Northern Ireland Protocol.

Q: What will be the impact on the QP release from Northern Ireland for EU Clinical Trials? We understand that EMA will accept batches QP released from NI and MHRA will impose a 'UK Only' text for batches of authorised products, but not for CT IMP batches. Is that your understanding too?
A: This is correct in that EU countries will accept IMPs QP released from NI MIA(IMP)s. However, the MHRA will also accept IMPs QP released from EU manufacturers if there is a UK MIA(IMP) QP oversight in place. For further information, please see: https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries/importing-investigational-medicinal-products-imp-from-countries-on-a-list-to-great-britain

Q: If products are released by EU QP and quarantined in EU at CMO can we market it in UK after 1 Jan 25 with old AW?
A: Any stock QP released prior to 1st Jan 2025 can continue to be supplied to market until expiry - usual guidance concerning quarantine of stock will apply.

Q: My client has products which are QP released in the EU (and warehoused there). In the scenario that they have UK-destined product which is (EU) QP Released before 1 January 2025, which does not include 'UK Only' on pack, then held in the EU warehouse, can this be then shipped to the UK-supply chain after 01/01/2025 (UK RPi in UK)? Or does UK-specific release include the UK RPi check too?
A: Any stock QP released prior to 1st Jan 2025 can continue to be supplied to market until expiry – the guidance doesn't go into this level of detail, therefore I would suggest it was ok to enter the supply chain as long as it was released before 1st Jan 2025.

Q: In what situation (post Jan 25) would there be a need for a PLNI pack?
A: Companies with an existing PLNI without a corresponding PLGB, may choose to retain this post Jan 2025 due to their commercial needs/plans for the relevant product. Additionally, MAH may choose to gain authorisation in NI

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via the MR/DC route to provide NI patients with access to a product that perhaps, for commercial/Regulatory strategy reasons, won't be available in the whole of UK until a later date.

Q: When you say all packaging must state 'UK Only', is there guidance for packs that are already in circulation?
A: All outer packaging must state 'UK Only' from the 1st Jan 2025. Any packs QP released prior to 1st Jan 2025 can continue to be supplied to market until expiry.

Q: Can PLGB packs updated with 'UK Only' be released before 1st Jan 2025?
A: Yes, however they cannot be distributed to Northern Ireland until after 1st Jan 2025 since Northern Ireland require FMD applied (unless on the NIMAR list).

Q: Can we release the product with 'UK only' without any notification to the MHRA?
A: No, you need a submission.

Q: Do we need to add 'UK Only' to the label in addition to the outer carton?
A: 'UK Only' is only required once and on the outer packaging. If this is a label then it will need to be added.

Q: Can we remain as part of the MRP?
A: Yes, however you still require 'UK Only' on the outer packaging. Additionally, if there are UK specific changes requested by the MHRA during an assessment, UK(NI) will need to withdraw from the MR/DCP.

Q: Can PLGBs be exported outside of the UK if 'UK Only' statement is applied to the packs?
A: This is a decision of the country of import and you will need to clarify with the relevant Health Authority.

Q: Will we need to update our licence number from PLGB to PL?
A: No, on the 1st Jan 2025, PLGBs will be converted to 'UK-wide' licences – do not update from PLGB to PL.

Q: Is a submission needed if we sticker?
A: Yes! You will need to submit the mock up to the MHRA as well as including the name of the MIA holder performing the stickering, who should also be named in Module 3. Note, this cannot be carried out by a wholesalers.

Q: Does the artwork have to be approved internally by 1st Jan 2025?
A: Not necessarily – this all depends on your manufacturing schedule, for example if you have a manufacturing run in September 2024 (with existing artwork) and the next run is in March 2025, then you have a little longer in which to implement. However, your company will likely still need a 6-month window to make the changes and, don't forget to make the submission to the MHRA by 31st December 2024.

Q: Do I need to make a submission for our non-marketed products?
A: No, however if the decision is made to market the product, updated mock ups will need to be submitted for approval at a later date.

Q: Where in the labelling text should we include 'UK Only'?
A: MHRA have stated this should be included in Section 7 'Other Special Warning(s)'.

Q: We are not due to be manufacturing in 2024, can the submission wait until 2025?
A: The MHRA guidance states that the latest date a submission can be made is 31st December 2024. You do have the opportunity to make a non-eCTD submission along with an annotated mock up, which is less time consuming, however you will need to follow this up within a eCTD submission and clean mock before 31st December 2025. Alternatively, you can contact the MHRA directly at RIS.NA@mhra.gov.uk to request agreement to delay.

Q: Is it sufficient to remove only the unique serial number but retain all other information in the 2D barcode?
A: Yes, it is just the unique reference number which mustn't be uploaded to EMVS.

While the information above is considered to be true and correct,
changes in guidance and/or experience may impact on the accuracy of the information.
Please refer to the relevant guidance for the latest information.