Questions and Answers on the Windsor Framework and medicines for human use (updated 25 October 2024)

This Q&A is not a comprehensive overview of the implications of the Windsor agreement, rather we are answering questions received from companies. Any questions not included in the document should be addressed to brexit@hpra.ie and we will update the document accordingly.

The Windsor Framework (WF)

1. **Q:** Which legislation implements the Windsor Framework for medicines?

   A: The WF was implemented in Regulation (EU) 2023/1182 and it is directly applicable from 1st January 2025.

2. **Q:** What is the significance of the WF for medicines on the Irish market?

   A : The WF removes the possibility for jointly labelled medicines with NI/GB/UK. This is because UK medicines will now be required to carry the words "UK only" on the outer packaging and will not be permitted to carry the 2-D matrix serialisation safety feature that has been uploaded to the EMVO repository as required by the Falsified Medicines Directive. Currently a number of national and a significant number of centralised products are jointly labelled for both the IE and NI/GB/UK markets.

Windsor Framework implementation timelines

1. **Q:** On what date does the WF become mandatory?

   A: The WF takes effect for medicines for human use on the 1st of January 2025.

2. **Q:** What happens to product on the market before that date?

   A: Any batches of joint labelled IE/UK medicines, batch released for the IE /UK markets, before 31st December 2024 can remain on the market until the expiry date of the medicines. This applies both in IE and the UK. In other words, the provisions of the WF only apply to product batch released after 31st December 2024.

Joint labels for national products between IE/UK

1. **Q**: Can joint outer labels between IE and the UK remain in place after the WF takes effect?

   A: No. product placed on the NI (and GB) market will carry the words "UK only" on the outer packaging and will be prohibited from carrying the 2-D matrix serialisation safety feature required by the Falsified Medicines Directive.

2. **Q**: Can the inner packaging and package leaflet remain the same between IE and the UK after the WF takes effect?

A: Yes. Where the information in the package leaflet and the immediate packaging remains the same in both jurisdictions apart from the administrative details (i.e. consistent with the authorisation in IE and UK), then the administrative details from both jurisdictions can be included on the package leaflet and inner packaging.

3. **Q**: Does an Article 61(3) application need to be submitted to the HPRA for assessment to remove UK/NI details when converting IE/UK or IE/NI joint packs to IE only packs?

   A: For national authorised products it is not necessary to submit an Article 61(3) application to the HPRA for assessment when removing or changing the administrative information for an EU member state (MS) or the UK placed within the 'blue box', which does not affect any other aspects of the layout and font size of packaging, labels and leaflet text (Section 4.3.1 of HPRA Guide to Labels and Leaflets of Human Medicines). For products authorised through the centralised procedure the marketing authorisation holder should submit, to the EMA, a dedicated notification under Article 61(3) of Directive 2001/83/EC.

   The guidance outlined in this Q&A also applies when product information is being updated to remove a local representative for NI or UK. An Article 61(3) application is not required for nationally authorised products but is required for centrally authorised products.

4. **Q:** Can medicines with IE/NI or IE/UK labelling be released to the Irish market post 1st January 2025?

   A: It is understood that this question relates to using pre WF approved (joint) packaging for the IE market only. Nationally and centrally authorised products which are in accordance with the Irish/EU authorisation can continue to be released on the Irish market using pre WF approved packaging with UK information, but the expectation is that this is a transitional provision, and the product outer packaging should be updated when other changes to the packaging are required. Marketing Authorisation Holders must have updated their labelling to remove all NI/UK administrative details by 31st December 2027. This only applies to the outer carton when the immediate label and/or the package leaflet is jointly shared with the UK.

5. **Q:** Over-labelling of the 'UK only' label:
   For non-prescription medicines will the HPRA accept the over-labelling of the 'UK only' label on the outer carton/bottle so that joint packs with the UK can be maintained?

   A: Yes, the 'UK only' label can be covered over with a label as long as the label is permanently attached to the outer carton/bottle and cannot be removed. The label must not cover any text on the carton/bottle and must not affect the readability of the outer labelling. The label must completely cover the 'UK only' label text.

   To register the over-labelling the MAH must provide updated mock-ups to the HPRA by way of an article 61(3) application. Over-labelling is considered a manufacturing operation and therefore this operation must be conducted in a site that holds a valid manufacturer's authorisation.

6. **Q:** Over-labelling of the 'UK only' label and addition of the 2-D matrix serialisation safety feature:
   For prescription only medicines will the HPRA accept the over-labelling of the 'UK only' label on the outer carton/bottle and the addition of the 2-D matrix serialisation safety feature so that joint packs with the UK can be maintained?

   A: Yes, the 'UK only' label can be covered over with a label as long as the label is permanently attached to the outer caron and cannot be removed. The label must completely cover the 'UK only' label text. In justifiable cases, the addition of the 2-D matrix serialisation safety feature is permitted as long as the label is attached to the outer carton/bottle and cannot be removed without being damaged. The over-label must fulfil the quality of the printing requirements set out in Article 6 of the Commission Delegated Regulation (EU) 2016/161 (case C 147/20, Novartis Pharma GmbH v Abacus Medicine A/S). The human readable text for the PC, SN, Lot and EXP Date will need to be placed beside the 2-D matrix serialisation safety feature.

   Over-labelling must not cover any statutory text on the carton/ bottle and must not affect the readability of other required labelling text. If there is an existing barcode on the IE/UK pack that could be confused by the end user with the 2-D matrix serialisation safety feature this should be covered over, ideally with the EU 2-D matrix serialisation barcode.

   Over-labelling is considered a manufacturing operation and therefore this operation must be conducted in a site that holds a valid manufacturer's authorisation and in accordance with Good Manufacturing Practices. To avail of the flexibility to add the 2-D matrix by way of an over-label the MAH must contact the HPRA using the Brexit@hpra.ie with a justification as to why this flexibility is needed. The HPRA will consider the justification and revert with our approval or otherwise.

   To register the addition of these over-labellings, the MAH must provide updated mock-ups to the HPRA by way of an article 61(3) application.

Product moving between Northern Ireland and Republic of Ireland

1. **Q**: Does the implementation on 1st January 2025 of the WF mean that NI will be strictly a third country where medicinal products are concerned?

   A: The WF introduces additional provisions relating to medicinal products for human use intended to be placed on the market in NI. It is the HPRA's understanding that aside from these additional provisions, the previous specific arrangements in relation to NI as reflected in previous HPRA guidance, EMA guidance and commission communications remain unchanged.

   As reflected in the Notice to stakeholders issued by the European Commission and the EMA in March 2020 following the withdrawal agreement and the NI protocol, that protocol includes specific provisions relating to NI which would differentiate NI from the standard approach that would apply in relation to a third country.

2. **Q**: What will be the situation in relation to medicines moving between the Republic of Ireland & Northern Ireland after the implementation of the WF?

A:

Medicines moving from Northern Ireland (NI) to the Republic of Ireland (IE)

Article 7 of Regulation (EU) 2023/1182 introduces a new provision which states that medicinal products as referred to in Article 1(1) of that Regulation shall not be moved from NI to a Member State or be placed on the market in a Member State.

Article 1(1) specifies that the scope of the Regulation includes medicinal products intended to be placed on the market in NI in accordance with Article 6 of Directive 2001/83/EC. Based on this, authorised medicines intended to be placed on the market in NI cannot be moved into IE or any other EU Member State. We therefore understand that parallel exports from NI will not be possible. Medicinal products not intended for or placed on the NI market can continue to be wholesaled, manufactured and batch released from NI to the EU.

Exempt medicinal products

The movement of UK or NI packs from NI to IE, intended to be supplied under Article 5(1) of EU Directive 2001/83/EC as exempt medicinal products (EMPs) will still be permitted where an authorised equivalent product is not available in Ireland, in line with the requirements outlined in the HPRA Guide to the Notification System for Exempt Medicinal Products.

These packs may not leave the Irish market, as their supply to IE from NI is based on EMP national provisions to facilitate such supply to Irish patients in circumstances where a specific medicine they require is not available in IE. To ensure this, IE wholesalers receiving UK or NI authorised packs from NI suppliers on this basis, should only supply to customers that are authorised to supply medicines to patients (e.g. hospital and retail pharmacies). Onward supply to other wholesalers is not permitted.

Medicines moving from the Republic of Ireland (IE) to Northern Ireland (NI)

The movement of medicines from IE to NI is not considered export from the EU.

All usual regulatory requirements apply i.e. that the product supplied is appropriately authorised for the intended market, or where it is supplied as an unlicensed medicine all local requirements of the destination market are met.

3. **Q**: Will products manufactured and QP released in Northern Ireland be considered as batch released for the EU market?

   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.

The Brexit Derogations

To prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, Directives 2001/20/EC and 2001/83/EC were amended to provide for derogations for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland. It was clearly specified that to ensure uniform application of Union law in the Member States, that the derogations applicable in Cyprus, Ireland and Malta would be of a temporary nature only. Directive 2022/642/EC amended Directives 2001/83/EC and 2001/2/EC. The derogations approved in Ireland will expire on 31st December 2024. After this time, all medicines released to the Irish market will need to be EU regulatory compliant. To assist MAHs with this change the following guidance is published.

Quality Control testing:

1. **Q**: Can QPs use quality control data generated in the UK prior to 11 pm on 31st December 2024, under a derogation, to batch release product for the Irish market in 2025.

   A: Yes, QPs can use quality control data generated in the UK prior to 11 pm on 31st December 2024, under a derogation, to batch release product for the Irish market in 2025.

Batch release:

2. **Q**: Can product that is availing of derogations that is batch released in the UK for the IE market prior to 11 pm on 31st December 2024 but is still in transit during / after the year end be placed on the IE market.

   A: Product that is batch released for the IE market prior to 11 pm on 31st December 2024 and dispatched for the IE market pre year end can be placed on the market post year end. This product can be received under a Wholesaler's Distribution Authorisation in Ireland if this was facilitated by a derogation prior to January 2025. Companies that have difficulties moving stock to IE prior to 31st December 2024 should contact the HPRA.