Questions and Answers on the Windsor Framework and medicines for human use

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 which amends Directive 2001/83/EC

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" 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 becomes 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 31 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 31 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: 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).

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

   A: It is understood that this question relates to using pre WF approved 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.

Product coming from Northern Ireland to 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 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: Art 7 of Regulation (EU) 2023/1182 introduces a new provision which states that medicinal products as referred to in Art 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. Art 1(1) specifies that the scope of the Regulation includes medicinal products intended to be placed on the market in NI in accordance with Art 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 MS. We therefore understand that parallel imports from NI will not be possible. However, products not intended for or placed on the NI market can continue to be wholesaled, manufactured and batch released from NI to the EU.

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.