**LETTER OF ANNOUNCEMENT**
**Clarifying the uploading requirements for packs intended for supply in Northern Ireland into the EMVS**

22nd February 2021

As stated in our previous announcement, the European Commission with its *Notice C (2020) 9264 on the Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period* confirmed that the placing of safety features foreseen in the Falsified Medicines Directive will be required for medicinal products placed in Northern Ireland, but not for products placed in any other part of the United Kingdom.

As a result, MAHs need to consider whether the marketing authorisation (MA) for the concerned medicine(s) covers the marketing of the medicine(s) in Northern Ireland, and then to add the safety features to the respective packs and load the data to the EU Hub accordingly. If the MA does not apply to Northern Ireland, then no pack data load is required.

**Northern Ireland uses the market code GB, so data needs to be uploaded to the EMVS market denoted by GB.** For example, single market packs intended for Northern Ireland should be uploaded to the market marked GB in the EMVS. **NI packs should not be uploaded to the IE market**, except where they are joint packs authorised and intended to be placed on the market in Ireland as well as Northern Ireland.

OBPs should take care to ensure the upload of the required data to the appropriate systems.

For more information on Brexit, such as frequently asked questions, please visit our Brexit Q&A.

In the event of any questions or uncertainty, please do not hesitate to contact our Helpdesk:

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**EMVO Team**

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