**LETTER OF ANNOUNCEMENT**
**EMVO's communication regarding the impact of Brexit and the Northern Ireland Protocol in the EMVS following the EU Commission's Notice**

23 December 2020

As mentioned in our previous announcement of the 5 November 2020, EMVO was expecting guidance from the European Commission and the Member States regarding the release/decommissioning of single market medicine packs for Great Britain or Northern Ireland, and multi-market medicine packs (packs with common labelling across two or more markets, including the UK) in the EMVS after 1 January 2021.

Today, 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*, provides some long-expected clarifications to minimise the impact of Brexit on concerned parties whilst maintaining necessary safeguards for the protection of the legal supply chain from falsified medicines.

More specifically, 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. According to the Notice, as of 1 January 2021, packs destined for Great Britain should be separated from packs destined for Cyprus, Ireland, Malta or Northern Ireland – even where the supply route goes through Great Britain.
This means that manufacturers and marketing authorisation holders will need to ensure the upload of the required data in the EMVS for Cypriot, Irish, Maltese and Northern Irish packs but not for packs with a final destination in any other part of the United Kingdom (Great Britain).*

With respect to packs exported from the European Union (EU) to any third country (e.g. United Kingdom), the Commission confirmed its intention **to amend Article 22 of Commission Delegated Regulation (EU) 2016/161**. As a result, it will no longer be required to decommission packs - in accordance with Article 22 - when such packs are exported from the EU to Great Britain.

However, the import of such non-decommissioned packs to the EU (via Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland) will be possible provided that:

- the wholesale distributor or the marketing authorisation holder established in the EU and responsible for the **export** of the medicinal product to the United Kingdom has **verified** the pack against the EMVS;
- the wholesale distributor **importing** the product into Northern Ireland, Ireland, Cyprus or Malta has **verified** the pack against the EMVS;

*By way of derogation, from 1 January 2021 to 31 December 2021 the obligation to decommission the unique identifier of medicinal products which the wholesaler intends to distribute outside of the Union shall not apply to products which he intends to distribute in the United Kingdom.

***Disclaimer***
*As negotiations between the European Commission, the UK Government, and potentially impacted market NCAs are still ongoing, the instructions to On-Boarding Partners may be subject to change.*

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

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