LETTER OF ANNOUNCEMENT
EMVO's communication regarding the impact of Brexit and the Northern Ireland Protocol in the EMVS

5 November 2020

EMVO has been working to manage the implications of Brexit (the UK's departure from the EU Internal Market rules) for the EMVS and its users. This was undertaken in close collaboration with concerned authorities and stakeholders, including the European Commission, as well as the most impacted National Medicines Verification Organisations (NMVOs).

Although the final Brexit negotiations continue, EMVO is working to ensure that as from 1 January 2021 the operation of the EMVS is adapted to the EU-UK Withdrawal Agreement and Northern Ireland Protocol (included as an Annex thereto) that makes certain provisions of EU law applicable "*to and in the United Kingdom in respect of Northern Ireland*".

At the end of September 2020, the EMVO Board decided that the existing UK system will remain connected and will become the UKNI MVS accessible for Northern Ireland (NI) End-Users from 1 January 2021.

As it stands, from 1 January 2021, the UK will no longer participate in the EU Internal Market, and FMD legislation will no longer apply in Great Britain (England, Scotland, Wales, the Channel Islands, and the Isle of Man). Northern Ireland will remain in the EU Internal Market, and therefore, FMD legislation will continue to apply in that region of the UK.

UK medicine packs released in the EU Internal Market prior to 1 January 2021 (legacy packs) can continue to be verified and decommissioned in the EMVS and require no additional action by On-Boarding Partners.

Furthermore, EMVO is seeking 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. During a call with the European Commission, the UK Government, and the affected Member States at the end of October, EMVO discussed the option of a potential grace period. This request is currently being reviewed. EMVO is expecting clarification and guidance later this month. Nevertheless, our shared objective remains to ensure FMD compliance while minimising disruptions to medicines supply in the EU Internal Market.

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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