EU Regulations 2019/6 and 2019/4 will not be implemented in Northern Ireland

News story

Details of the implementation of EU Regulation 2019/6 and EU Regulation 2019/4 in Northern Ireland.



In line with the <u>Government announcement on maintaining standstill</u> <u>arrangements</u> in September 2021, and while discussions on veterinary medicines continue, EU Regulation 2019/6 and EU Regulation 2019/4 will not be implemented in Northern Ireland from 28 January 2022, except for areas previously agreed in relation to the operational aspects concerning applications for new marketing authorisations and associated life-cycle management (variations, renewals, QRD text and pharmacovigilance).

Recognising that EU medicines approval processes are essential to maintain availability of medicines for the UK, as an interim measure we have established ways to bridge this gap between the EU Legislation and the current VMR, as they have effect in GB and NI, whilst still respecting both sets of legislation. Details of these mitigations are on our <u>Information Hub</u>.

The operation of the Protocol will continue on the current basis to give certainty and stability to businesses while UK-EU discussions continue.

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