BREXIT IMPACT SUMMARY

Impact Area	EU Position	UK Position
New marketing authorisations, centrally authorised products (CAPs).	Must have marketing authorisation holder (MAH) in the EU/EEA.	Must apply for separate UK authorisation using the same information as for EU authorisation.
New marketing authorisations, mutual recognition procedure (MRP)/decentralised procedure (DCP).	UK cannot be a Reference Member State (RMS) or Concerned Member State (CMS)	Need separate UK application.
Existing marketing authorisations.	CAPs must have an MAH in the EU. Where UK was (co-)rapporteur this has been reassigned to other EU/EEA Member States. If MRP/DCP, then RMS/CMS cannot be the UK. If UK is the RMS, need to transfer to an RMS in the EU, usually to one of the CMSs. MAH must be located in the EU/EEA.	CAPs automatically granted a UK authorisation: one year to provide MHRA with baseline data. MAH must be located in UK by end 2022. Need a contact in the UK from 1 Feb. 2021.
Batch testing and QP certification.	Batch testing must be within the EU/EEA or mutual recognition agreement (MRA) country (no MRA with UK). QP certification must be within the EU/EEA. From 1 Jan. 2022 product exported to Northern Ireland will need re-testing and QP certification in Northern Ireland.	Testing must be within the EU/EEA, MRA country or UK. No additional QP certification required in UK if certified by a QP in the EU/EEA but wholesalers importing from EU/EEA need to name an RPi on WDA by 1 Jan. 2023.
Batch testing, product manufactured in EU/EEA.	Testing must be performed within the EU/EEA.	No additional testing is required on import to UK until 1 Jan. 2023.
Batch testing site, product manufactured in a third country and no MRA in place with the EU.	Testing must be within the EU/EEA.	Testing may be in the EU/EEA or UK. No additional testing required in UK if tested in EU/EEA until 1 Jan. 2023.
Access to EU Medicines Agency's IT systems such as EudraVigilance.	UK will no longer have access to EudraVigilance.	UK has own system; ADRs to be reported to MHRA.
Good Manufacturing Practice and Good Distribution Practice.	EU Regulations and guidance apply.	UK will continue to follow EU guidance at least until 1 Jan. 2023.

Northern Ireland effectively remains within the EU so many changes only impact the UK