

Brexit Transition Period Checklist



1. Supply Chain

With regard to the supply of medicines and medical devices, companies are requested to:

- Map your supply chain to determine Brexit exposure, including route to market.
- Assess how Brexit may impact your ability to supply the Irish market.
- Take the necessary steps to ensure sufficient stock levels and continuity of supply both in the period leading up to 31 December 2020 and post the transition period.
- Review stocks at wholesale level and ensure arrangements are in place to allow for timely replenishment of such stocks including custom requirements where applicable and allowing for potential delays during transportation.



2. Customs

- Register with Revenue for an EORI number.
- Understand what is needed to fulfil customs declaration requirements.
- Consider a customs agent/broker or in-house management to complete declarations.
- Consider what authorisations or simplifications about customs procedures might be relevant.
- Determine whether you have to comply with UK customs requirements.
- Identify classification codes for devices/products/ingredients.
- For suppliers sourcing devices from the UK, prepare for the additional responsibilities you will have as an importer when sourcing products from the UK post-Brexit.



3. Medicines Regulatory Compliance

Ensure all activities are being undertaken to meet EU regulatory requirements by 31 December 2020. These include the following:

- Transfer of UK MAH to one based in the EU/EEA.
- Relocation of batch release site in the UK to the EU/EEA.
- Relocation of QC testing sites in the UK to the EU/EEA.
- Transfer of UK RMS to an EU/EEA based RMS.
- The nominated QPPV must be based in an EU/EEA Member State.
- For clinical trials, transfer of any UK based sponsor or legal representative and the site of batch release to the EU/EEA.
- GMP certificates issued by the MHRA and VMD will be considered as part of a risk based approach to confirm the Union GMP compliance in regulatory submissions.



4. Medical Devices

Ensure all activities are being undertaken to meet EU regulatory requirements by 31 December 2020. These include the following:

- For devices certified by UK notified bodies – confirm with the manufacturer that they will transfer to an EU-27 notified body by 31 December 2020 and that there is a plan for continued certification of the devices.
- For devices manufactured in the UK or with UK Authorised Representatives – ensure an authorised representative has been designated in an EU-27 Member State.
- For clinical investigations, transfer of any UK based sponsor or legal representative to the EU/EEA.



5. Further Information

www.hpra.ie/brexit

www.revenue.ie