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Northern Ireland Protocol (NIP) Impact on Medical Devices

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What is the Northern Ireland Protocol?

Part of the Withdrawal Agreement in place with the UK providing specific arrangements for Northern Ireland in relation to customs and the regulation of goods.

In place initially for four years and may be renewed every four years thereafter;

EU legislation will continue to apply in Northern Ireland, including medical devices legislation.

Therefore, devices placed on the market in Northern Ireland have to comply with EU medical devices legislation;

Guidance: Commission Notice to Stakeholders March 2020, Section C

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Key Issues For Economic Operators

- Authorised Representatives
- Notified Body Certificates
- Distribution & Importation
- Labelling
- Registration

Authorised Representative (AR) Requirements

Authorised Representatives

- From 1st January 2021, UK manufacturers must have an AR designated in the European Union.
- Economic Operators based in Northern Ireland are recognised by the EU-27 under the NIP, this includes ARs.

Notified Body (NB) Certificates

Notified Body Certificates*

- From 1st January 2021, UK NB certificates will no longer be recognised by the European Union.
- Devices placed on the EU-27 market or the Northern Irish market requiring NB oversight must be certified by an EU-27 notified body.
- In accordance with the NIP, a NB established in Northern Ireland may certify devices.
- Any certificate issued by a NI NB are only valid for Northern Ireland.
- Certificates issued by a NI NB are not valid in the EU.

* There are currently no NBs designated in Northern Ireland

Distributors & Importers

Distribution & Importation

- Devices manufactured in Northern Ireland (NI) and shipped to the EU are not considered imported products for the purpose of labelling and economic operator identification;
- In accordance with the NIP, EU importers established in NI will continue to be recognised as EU economic operators.
- Therefore, distributors procuring devices from NI will not take on the role of a medical device importer;
- However, if a distributor procures devices from an entity based in Great Britain they will become the device importer, regardless of whether the devices are transported though Northern Ireland.

Labelling Requirements

Labelling

- Devices placed on the EU-27 market must be CE marked and fulfil the labelling requirements set out in the medical devices legislation.
- Under the NIP devices placed on the Northern Irish market must be CE marked and fulfil the labelling requirements set out in the medical devices legislation.
- Please consult the MHRA for guidance relating to the UK market.

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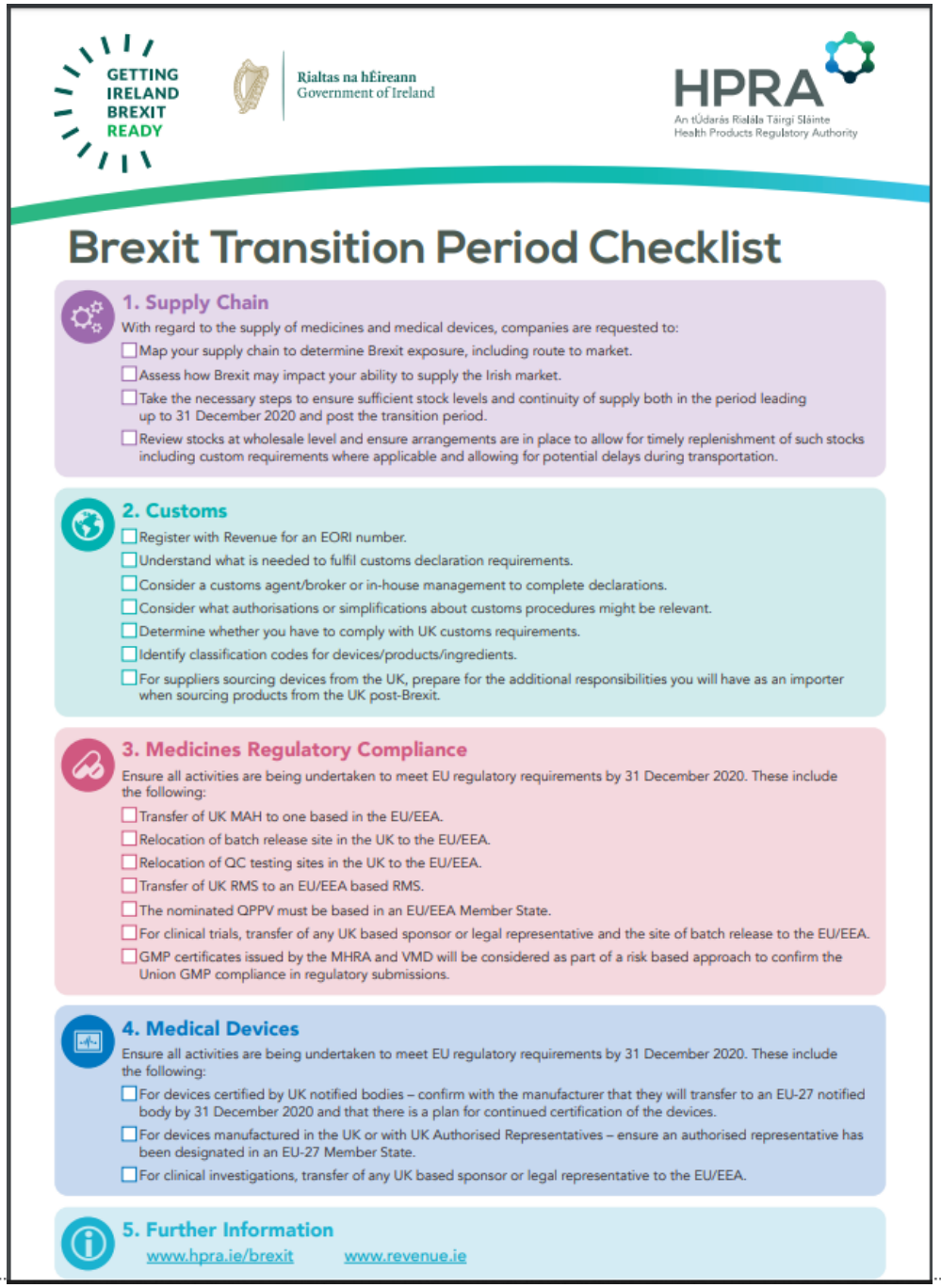
Registration Requirements

Registrations

- Economic Operators established in the Republic of Ireland must register with the HPRA.
- All other economic operators must register with their Competent Authority (CA). The CA for Northern Ireland is the MHRA.

HPRA's [Brexit Checklist]



GETTING IRELAND BREXIT READY

Rialtas na hÉireann
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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

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Thank You

Brexit related queries can be sent to devices@hpra.ie