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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

BREXIT-Medical Devices Planning

Key issues for Medical Devices

1. Notified Body Certification
2. EU Authorised Representative
3. Registration requirements
4. Labelling
5. Potential shortages of essential devices for patients
6. Delay or challenges to supply chain

Impact on Medical Device from January 2021

UK Certificates:

- Will no longer be recognised for new devices manufactured and placed on the EU-27 market after 31st December;
- Devices must be certified by EU-27 NB.

Authorised Representatives (AR)

- UK based AR will no longer be recognised as an EU economic operator- must be located in EU-27*
- UK based manufacturers must designate an EU-27 AR

For Northern Ireland based entities, please refer to the Commission Notice to Stakeholders, Section C

Placing on the Market- Definition

- Placing on the market is defined as the "*first making available on the market*" (by the manufacturer).
- The device is in the distribution chain. This requires a legal or financial transaction.
- Making available on the market is defined as "*any supply of a product for distribution, consumption, or use on the [...] market in the course of a commercial activity, whether in return for payment or free of charge*

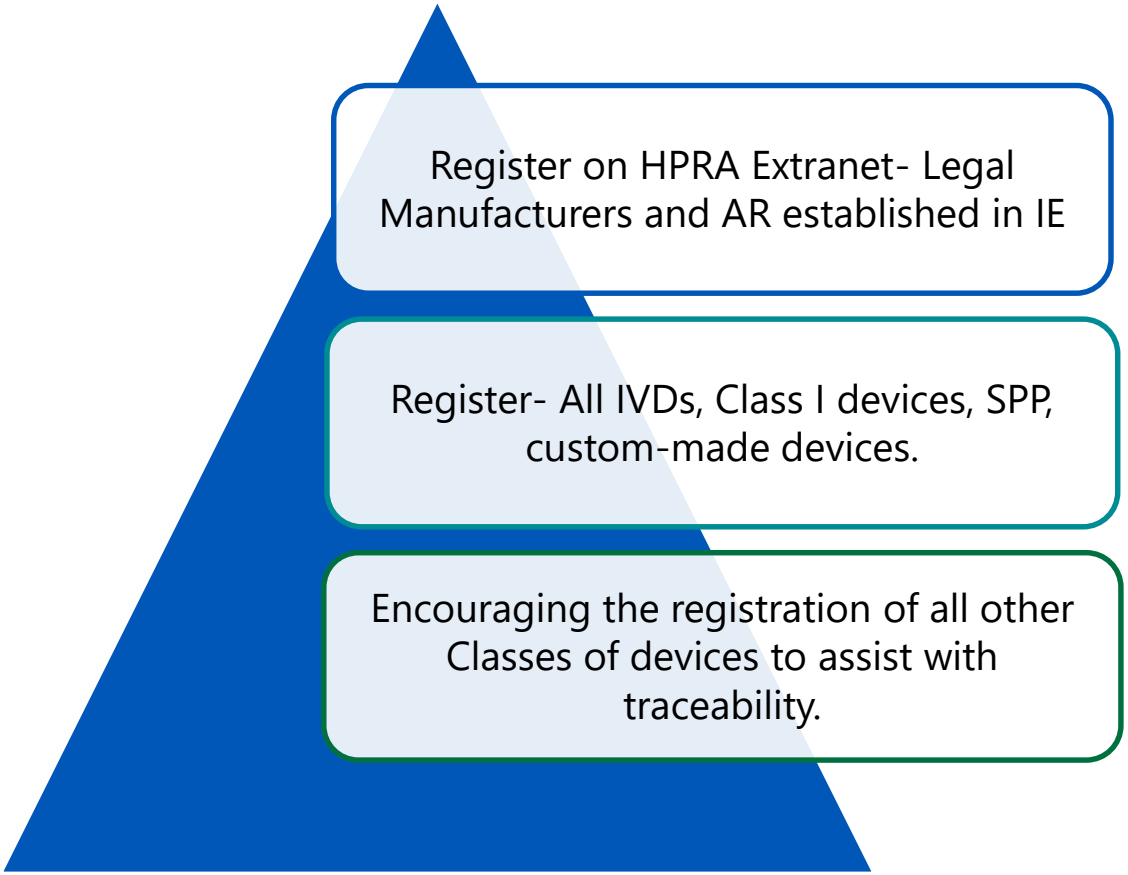
Authorised Representative Requirements

Establishing an EU Authorised Representative (AR)* in Ireland

- Register organisation with HPRA.
- Written mandate between MFR, outgoing AR and incoming AR.
- Plan for transfer – Responsibilities, timelines, labelling, exchange of information.
- Listing of devices impacted (all classes)
- Work towards MDR/ IVDR obligations (May 2021/2022).

* Same approach envisaged for legal manufacturers established in Ireland

Registration Requirements



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Labelling Updates

Update notified body numbers for devices manufactured from 1st January 2021.

Update authorised representative details on device label and documentation.

Provide the HPRA with a transition plan for device labels and keep the HPRA updated on the progress.

Consider any labelling changes required for the MDR/IVDR.

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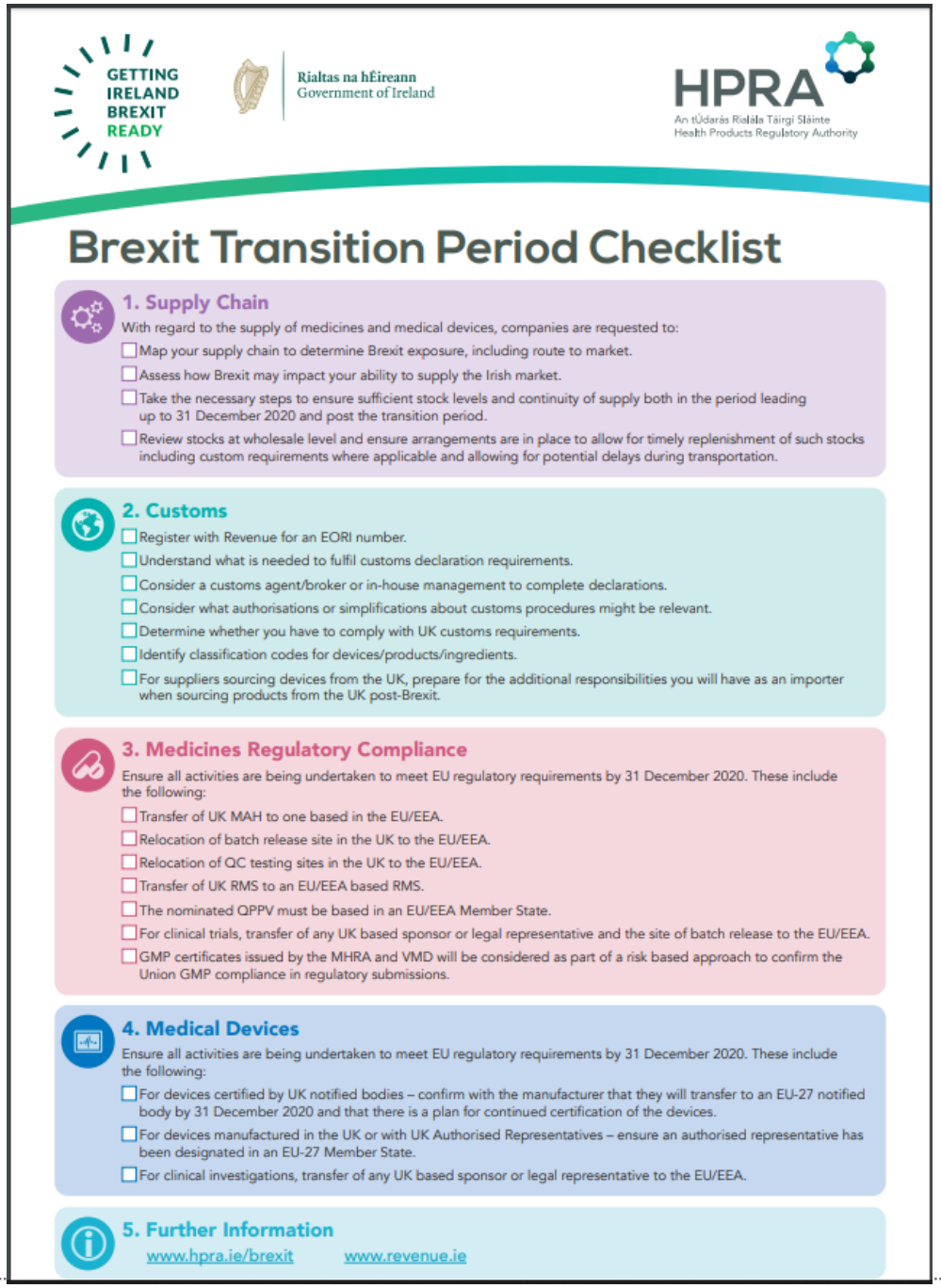
Potential Shortages of Essential Devices

- What are the essential Medical Devices?
- Identify Devices sourced in the UK – manufacturer/ distributor
- Identify devices certified by UK notified bodies
- Examine supply chain & transit routes – explore alternatives
- Liaise with customs
- Raise awareness with HPRA, HSE & HCPs

HPRA's [Brexit Checklist]



GETTING IRELAND BREXIT READY

Rialtas na hÉireann
Government of Ireland

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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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Conclusion

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Thank You

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