ARTHUR COX

Group Briefing
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Portable Products: *Moving your Marketing Authorisations or CE Marks to Ireland*

Ireland Client Service Law Firm of the Year 2018
Chambers Europe Awards

Ireland Law Firm of the Year 2018
International Financial Law Review (IFLR) Europe Awards

Advised on Equity Deal of the Year 2018 – Allied Irish Banks IPO
International Financial Law Review (IFLR) Europe Awards

Ireland Law Firm of the Year 2018
Who's Who Legal

Ireland Law Firm of the Year 2017
Chambers Europe Awards

Best Firm in Ireland 2018, 2017 & 2016
Europe Women in Business Law Awards

Best National Firm for Women in Business Law 2018, 2017 & 2016
Europe Women in Business Law Awards

Best National Firm Mentoring Programme 2018, 2017 & 2016
Europe Women in Business Law Awards

Best National Firm for Minority Women Lawyers 2018
Europe Women in Business Law Awards

Changing political and legal landscapes are prompting life sciences companies to review the location of their regulatory authorisations. Much of this is driven by EU regulatory requirements that necessitate an EU/EEA presence.

REASONS TO INCORPORATE IN IRELAND

- EU Member State
- English speaking
- Common law legal system
- Well-respected regulators
- Highly skilled personnel
- Compelling global life sciences presence
- Competitive tax rates
- IP incentives

HOW TO INCORPORATE?

Irish incorporation is a fairly straightforward process. Once you have identified the type of company you wish to set up (e.g. LTD, Unlimited or DAC), the following is required by the Irish Companies Registration Office (the "**CRO**") prior to incorporation:

1. Constitution or Memorandum and Articles of Association
2. Form A1 specifying the Company's name, registered office address, principal activity, various details of the directors and secretary and the company's subscribers and their shares; and
3. A fee of €100 (or €50 if done electronically).

WHAT DO YOU NEED TO KNOW?

a. The Company must have a registered address in Ireland for correspondence and a place of business.

b. The preferred name should be pre-cleared with the CRO to confirm availability.

c. A Constitution for the Company must be prepared and filed with the CRO. Pre-authorised forms of Constitutions allow for speedy processing.

d. The company must have at least one director (and at least two if a company type other than a LTD is used). The board of the company will need an EEA resident director, or an insurance bond will need to be put in place.

e. The company must also have a company secretary.

HOW LONG DOES IT TAKE?

Once the complete paperwork is filed, there is an average 5 working days' time frame for incorporation if a standard Constitution is used. If a tailored constitution is used, the CRO may take up to 2 weeks to process the incorporation.

HOW TO MAINTAIN/TRANSFER REGULATORY AUTHORISATIONS?

Much of the momentum behind life sciences companies establishing a presence in Ireland is for regulatory purposes. The following table sets out a few conditions and tips to keep in mind if you are going through a regulatory change.

	TRANSFER OF MARKETING AUTHORISATION TO IRISH ENTITY	CHANGING RMS TO HPRA	NEW CE CERTIFICATE/ TRANSFER OF TECHNICAL FILE/ CERTIFICATE TO IRISH NOTIFIED BODY (NB)	APPOINTMENT OF AUTHORISED REPRESENTATIVE (AR)
1	Exact process depends on type of procedure used (e.g. centralised, decentralised, national)	HPRA very willing to act as RMS where Ireland was previously CMS	Transfer process governed by a contractual arrangement between the manufacturer, the old NB and the new Irish NB	Non-EU manufacturers of devices must appoint an AR within the EU
2	MAs are transferred to a new company number. A Certificate from the CRO will be required	No fees will apply to the above transfer process	Expect fresh review of the Technical File and documents	A written legal agreement is required
3	PA numbers also change which could have labelling/packaging implications. Alternative arrangements can be discussed with the HPRA/EMA	Simplification of the transfer allowed (can bundle applications)	To date, the NSAI is the only accredited NB in Ireland	Timing: An AR can be appointed relatively quickly but contractual negotiations likely to take longer due to new obligations in MDR/IVDR
4	HPRA accepts bulk transfers with reduced fees	Timing: Engage early with the HPRA (no later than 30 March 2019). Can be completed in a matter of days.	Timing: With MDR/ IVDR, NBs are experiencing resource and time constraints. Early contact is advised	
5	Timing: Two weeks, or earlier by agreement with the HPRA			

HOW CAN WE HELP?

Arthur Cox offers an incorporation service along with company secretarial and registered address services. Our regulatory team can also guide you through the regulatory change processes.

KEY CONTACTS

If you require advice or further information, please contact Colin Kavanagh. or Ciara Farrell.

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