Irish Tax Firm of the Year
European M&A Tax Deal of the Year
International Tax Review 2016

European Law Firm of the Year
The Hedge Fund Journal 2015

Financial Times 2012-2015
Matheson is ranked in the FT’s top 10 European law firms 2015. Matheson has also been commended by the FT for corporate law, finance law, dispute resolution and corporate strategy.
## Contents

1  Introduction  
2  Why Invest in Ireland?  
3  Ireland: An Overview  
4  Grants and Other Fiscal Incentives  
5  Establishing in Ireland  
6  Taxation  
7  Employment and Labour Law  
8  Real Estate, Planning and Environmental Law, Construction and Energy  
9  Intellectual Property and Technology  
10 Life Sciences Regulatory  
11 How Can Matheson Help You?
Introduction
Introduction

Over 1,150 international companies have operations in Ireland. These companies are involved in a wide range of activities and sectors including technology, pharmaceuticals, biosciences, financial services and manufacturing. The attraction of Ireland as an investment location can be attributed to the positive approach of successive Irish Governments to the promotion of inward investment, its membership of the European Union ("EU"), a very favourable corporate tax rate and a skilled and flexible labour pool.

The purpose of this Guide is to provide an introduction to the major commercial and legal issues to be considered by international companies establishing business operations in Ireland and it provides general observations and guidance in relation to the many questions we have encountered from clients. Particular businesses or industries may be subject to additional legal requirements and specific advice may be required in these circumstances.

If you are considering Ireland as a location for your business we look forward to hearing from you.
Why Invest in Ireland?
In 2014, Forbes ranked Ireland one of the best countries in the world for business. Ireland has succeeded in attracting some of the world’s largest companies to establish operations here. This includes some of the largest firms in the global technology, pharmaceutical, biosciences, manufacturing and financial services industries.

They are in Ireland because Ireland delivers:

- low corporate tax rate – corporation tax on trading profits is 12.5% and the regime does not breach EU or OECD harmful tax competition criteria;
- regulatory, economic and people infrastructure of a highly-developed OECD jurisdiction;
- benefits of EU membership and of being the only English-speaking jurisdiction in the eurozone;
- common law jurisdiction, with a legal system that is broadly similar to the US and the UK systems;
- refundable tax credit for research and development activity and other incentives; and
- extensive and expanding double tax treaty network, with over 70 countries, including the US, UK, China and Japan.

Our experience, together with research carried out by the Economist Intelligence Unit on behalf of our firm, indicates that it is the unique combination of these factors, and not one specific element, which attracts investment to Ireland. While other countries may be competitive in some of the areas highlighted above, Ireland’s ability to create a compelling suite of both tangible factors (such as taxation and the regulatory framework) and more intangible elements (such as a “can do” attitude to business) is generally cited as central to its ability to attract investment over other EU countries.
Ireland: An Overview
Some of the largest companies in the world have located in Ireland, including:

9 OUT OF THE TOP 10 GLOBAL ICT CORPORATIONS
13 OUT OF THE TOP 15 GLOBAL MEDICAL TECHNOLOGY COMPANIES
10 OF THE TOP 10 “BORN ON THE INTERNET” COMPANIES
9 OUT OF THE TOP 10 GLOBAL PHARMACEUTICAL COMPANIES
MORE THAN 50% OF THE WORLD’S LEADING FINANCIAL SERVICES ORGANISATIONS
9 OUT OF THE TOP 10 GLOBAL SOFTWARE COMPANIES

The Economist Intelligence Unit report on “Investing in Ireland: a survey of foreign direct investors”, commissioned by Matheson, examines the key factors that bring foreign investment to Ireland. The report identified four cornerstones to Ireland’s FDI offering:

- access to the EU internal market
- the overall taxation infrastructure
- the ability to supply a skilled pool of labour
- a stable legal and fiscal framework
Population
The population of Ireland now exceeds 4.5 million people.

Geography
Ireland is an island situated off the north west of the European continent. Dublin, which is on the east coast, is the capital city and has a population of over one million people.

It is one hour by air from London and 90 minutes from Paris and Brussels.

Language
English is the main language, making Ireland the only eurozone country in which English is the principal language.

Political and legal system
Ireland is a stable parliamentary democracy with a written constitution and two houses of parliament. While the President is the constitutional Head of State, the powers and functions of the Presidential office are largely ceremonial. The Government is elected for five-year terms and controls the legislative and political process. Ireland is a member of the EU and the United Nations. Irish law is based on common law, legislation, the Irish Constitution and EU law. Ireland has a very similar legal system to the UK and the USA.

Northern Ireland, as part of the United Kingdom, operates in a separate political and legal system which is not addressed in this Guide.

Economy
The currency of Ireland is the euro. Over the past decade, economic growth rates in Ireland have been consistently among the highest of OECD countries (countries in the Organisation for Economic Cooperation and Development).

Irish Government policy has been and continues to be directed towards the creation of a stable economic environment that is supportive of the needs of business. Over the last ten years, the number employed in industry and services has increased significantly and expansion has been particularly rapid in the areas of computer software/hardware, electronic engineering, food, pharmaceutical, healthcare and consumer products.

Transport infrastructure
International and internal transport services are well developed. The island of Ireland has a number of large ports and there are international airports in Dublin, Belfast, Derry, Shannon (near Limerick) and Cork. There are also regional airports in Donegal, Galway, Kerry, Knock, Sligo and Waterford (which operate some international routes). Most European cities are accessible within two to three hours flying time. Ireland has a developed public transport infrastructure and has an excellent network of main and secondary roads linking the major population centres.

Financial infrastructure
Ireland has a very well developed and sophisticated banking and financial services infrastructure with established experience in handling the requirements of international companies. The banking sector is regulated by the Central Bank of Ireland. Over half of the world’s top 50 banks have operations in Ireland.

Pro-business infrastructure
Ireland is recognised as one of the most attractive locations for international companies to access the EU internal market. The 2015 World Bank “Doing Business” report ranks Ireland in the top 10% of the 189 economies surveyed, while the 2010 World Bank “Investing across Borders” report states that Ireland:

• is among the most open to foreign equity ownership (of high income OECD companies); and
• has “one of the simplest and shortest processes” to establish a foreign-owned limited liability company (among high-income OECD countries).
Grants and Other Fiscal Incentives
Grants and Other Fiscal Incentives

The Irish Government actively encourages international companies to choose Ireland as a European base. Part of the incentive package offered can be state financial assistance, in the form of grants, to defray start-up or other costs. The Industrial Development Authority ("IDA") is Ireland’s FDI agency and has partnered with over 1,150 entities in establishing and expanding their Irish presence. A range of other supports, both financial and non-financial, are available from Government departments, offices and agencies.

What type of grants are available from the IDA?
A variety of grants are available and can be specifically tailored to meet the needs of each company. Cash grants do not have to be repaid save in certain agreed circumstances. In certain “regions” approved by the EU for Regional Investment Aid (aid based on the geographic location of an investment), aid may be given in the form of capital grants for the acquisition of fixed assets (that is, site purchase and development, buildings and new plant and equipment). In certain cases, aid may also be available for the acquisition of intangible assets such as patent rights, licences and know-how. The subsequent disposal of grant-aided assets is invariably restricted by agreement. Alternatively, regional aid may also be granted in the form of employment grants which are linked to the amount of each full-time and permanent job created and will vary depending on the location of the project and the activities to be undertaken.

What is the application procedure for IDA grants?
The process can take a number of weeks and involves the preparation and submission of a formal business plan to the IDA, together with subsequent meetings and negotiations between the applicant and the agency. In order to be considered for grant incentives, an applicant must satisfy the IDA that the financial assistance is necessary to ensure the establishment or development of the operation and that the investment proposed is commercially viable and will provide new employment.

If the application is approved and an incentive package is agreed, a grant agreement is then entered into between the IDA, the Irish entity and/or its promoter/parent company. This contract sets out the terms on which the grant aid is given and will vary from case to case.

How and when is the grant aid paid?
Grants are paid once the relevant expenditure is incurred. When a claim for a grant payment is received by the IDA, it is assigned to a designated executive in their grants administration department who liaises with the client company to make sure that the grant is paid as quickly and efficiently as possible. In order to claim grants, the company is usually obliged to provide certain specified information to the IDA including, for example, copies of signed employment contracts confirming the appointment of full-time permanent staff for the payment of employment grants. An auditors’ certificate is usually required to support all claims for the payment of grants. It is important for the company to maintain adequate records to facilitate this process.
Establishing in Ireland
Establishing in Ireland

Setting up a company

Company law reform
The Companies Act 2014 (the “2014 Act”) came into force on 1 June 2015. It marks a significant development in the strategic reform of Irish company law and represents a strong desire on Ireland’s part to ensure that there is a modern company law regime in place that will further enhance Ireland’s attractiveness as a place to do business. Matheson was actively involved in the progression of the 2014 Act through the legislature.

What type of companies are available under Irish law?
The two main types of company in Ireland are private companies and public companies. The vast majority of companies registered in Ireland are private companies limited by shares. They are by far the most popular form of business entity for inward investment projects. The shareholders of a private limited company have limited liability. Public limited companies are typically used where securities are listed or offered to the public.

The 2014 Act provides for two types of private limited company; a new model company (“LTD”) with simplified constitutional and governance structures, and a designated activity company (“DAC”) which is close in form to the private limited company under the old regime and which also benefits from certain reforms introduced by the 2014 Act. Existing private companies have an 18-month transition period (to 30 November 2016) to convert into one of the new company types.

What is the procedure for incorporation and how long does it take?
To incorporate a private company limited by shares, certain documents must be publicly filed with the Irish Companies Registration Office (“CRO”). These include details of the proposed name of the entity, the shareholders, directors and company secretary. The completed documentation together with the constitution are filed with the CRO.

Under an express incorporation scheme, it is possible to incorporate a company within five working days. Outside of the express scheme, it can take approximately two to three weeks for a company to be incorporated.

Can we choose any name we want for an Irish company?
Not necessarily, as there are restrictions on the choice of company name. The CRO may refuse a name if it is identical, or too similar, to the name of an existing company, if it is offensive or if it would suggest State sponsorship. Names which are phonetically and/or visually similar to existing company names may also be refused by the CRO. This includes names where there is a slight variation in the spelling. It is generally recommended that company names include extra words so as to create a sufficient distinction from existing names.

Registration does not give the company any proprietary rights in the company name. As well as searching the Register of Companies, it can also be important to check any proposed name against the names on the Irish Business Names Register and Irish and EU Trade Marks Registers (and any other relevant registers, depending on where it is proposed to carry on business). This is to ensure that the proposed company name does not conflict with an existing business name or trade mark, since the entity claiming to have a right to that name or mark could take legal action to protect its interest.

It should also be noted that certain names cannot be used unless approved by relevant regulatory bodies. By way of example, the words “bank”, “insurance”, “society” and “university” cannot be included in a company name unless prior permission is obtained from the relevant regulatory authority.

Can we reserve a company name in advance?
Company names may be reserved for a period of up to 56 days in advance of incorporation.

Is the company obliged to carry on an activity in Ireland?
A company will not be incorporated in Ireland unless the company will, when registered, carry on an activity in Ireland. A declaration confirming this must be completed and filed with the incorporation documents at the CRO.

Corporate Governance

What is the management and governance structure of an Irish company?
The management of a company is nearly always delegated to the board of directors. All companies, other than LTDs, must have a minimum of two directors. The secretary may be one of the directors of the company. The 2014 Act allows an LTD to have one director but, in that case, there must be a separate company secretary. A body corporate may act as secretary to another company, but not to itself. A body corporate may not act as a director. The directors of a company have a wide range of responsibilities under Irish law. They are obliged to act in the best interests of the company and to ensure that the company acts in compliance with Irish company law. The 2014 Act codified directors’ duties in a non-exhaustive list and introduced a new obligation for directors of PLCs and large private companies to prepare an annual compliance statement in relation to company and tax law and to review compliance measures annually. The Office of the Director of Corporate Enforcement has published an information booklet on Company Directors and a copy is available to download at www.odce.ie.

Are there residency requirements for directors?
At least one of the directors of an Irish company must be a resident of a Member State of the European Economic Area (“EEA”). Insofar as it is the person’s residence in Ireland that falls to be determined, a person must have been present in the State for a period amounting in aggregate to 183 days or more during the 12 months or 280 days over the 24 months (excluding 30 days or less in any one year) preceding the relevant date in order to qualify as “resident”.

An EEA resident director is not required where the company posts a bond in the prescribed form, to the value of €25,395. The bond provides that, in the event of a failure by the company to pay a fine imposed in respect of an offence under company law or a penalty under tax legislation, an amount of money up to the value of the bond will be paid by the surety in discharge of the company’s liability. The bond facility is available from a number of insurance companies in Ireland and the (non-refundable) premium payable for a two-year bond is approximately €1,600.

In addition, a company is not required to have an EEA resident director (or a bond in lieu) where the company holds a certificate from the CRO confirming that the company has a real and continuous link with one or more economic activities that are being carried on in Ireland. This option is only open to companies post-incorporation.

What are the post-incorporation obligations?
Set out below is a brief summary of the principal obligations. Further details can be provided on incorporation. Fines and other sanctions can be imposed on a company and any officer of a company where the relevant obligations are not met.

www.matheson.com
Maintenance of statutory registers
Various statutory registers and books of account must be maintained by a company under Irish company law. The registers required include: register of members, register of directors and secretaries, register of directors’ and secretaries’ interests in shares and debentures, and a register of debenture holders. A company is also obliged to keep minutes of its general meetings and the directors are also under an obligation to keep minutes of directors’ meetings. Certain registers are open to inspection by members of the general public.

In addition, Irish company law requires the directors to prepare financial statements for each financial year which give a true and fair view of the state of affairs of the company and of the profit or loss of the company for that period. In preparing those financial statements, the directors are required to:

(a) select suitable accounting policies and apply them consistently;
(b) make judgements and estimates that are reasonable and prudent; and
(c) prepare the financial statements on a going concern basis, unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the company. The directors must ensure that the financial statements are prepared in accordance with either International Financial Reporting Standards (IFRS) or with accounting standards generally accepted in Ireland. The consolidated financial statements of EU listed companies that are incorporated in Ireland or elsewhere in the EU must be prepared in accordance with IFRS.

Auditing financial statements
The annual financial statements of Irish companies are required to be audited by a registered auditor, subject to limited exceptions. The audit includes an examination, on a test basis, of evidence relevant to the amounts and disclosures in the financial statements. It also includes an assessment of the significant estimates and judgements made by the directors in the preparation of the financial statements, and of whether the accounting policies are appropriate to the company’s circumstances, consistently applied and adequately disclosed.

There are exemptions from audit for certain smaller companies. The 2014 Act extended the audit exemption to certain group structures and to dormant companies.

Irish legislation requires auditors to report to the relevant authority certain instances of their clients, or officers, committing indictable offences under Irish company law and to report any suspicions of theft, fraud or money laundering in their client companies.

Annual return filing
Companies must deliver an annual return to the CRO at least once a year. The annual return contains details of the company’s directors, capital and the auditor registration number. The annual return is required to be made up to the company’s annual return date ("ARD") and filed with the CRO within 28 days of that date. A company’s first ARD is the date which is six months after its incorporation. It is possible to change, and in some cases extend, a company’s ARD. A company’s audited financial statements must be annexed to a company’s annual return except the first annual return. Smaller companies may file abridged financial statements that provide less information than the annual financial statements prepared for the shareholders. In addition, an Irish company that is a subsidiary of an EU parent may file the consolidated financial statements of the parent instead of its own financial statements, provided the EU parent company guarantees the liabilities of the Irish subsidiary. A further optional exemption to the consolidation obligation applies where the Irish company is itself a subsidiary of another undertaking established outside the EEA (so, for example, an Irish holding company whose parent in turn is a listed US company). Where certain conditions are satisfied, the non-EEA parent company’s group accounts (together with the Irish company’s stand-alone accounts) can be filed as an alternative to the Irish company filing consolidated accounts. The filing of audited financial statements does not currently apply to certain categories of private unlimited companies.
Establishing in Ireland

Obligations to publish company name and directors details
A company must ensure that its name, registered address and registered number are mentioned on all business letters of the company and that its name is stated on all cheques, invoices and receipts. For private limited companies and public limited companies this information must also be displayed on the company’s website and certain electronic communications (for example, email, letters and electronic order forms). The names of directors and their nationality (if not Irish) must be included on all business letters on or in which the company’s name also appears. A company is also required to paint or affix its name in a conspicuous place, in legible letters, on the outside of every office or place in which its business is carried on.

Directors’ residential addresses
It is possible in limited circumstances for the residential address of a director to be withheld from the public register at the CRO. This exemption applies where the personal safety or security of the director or other company officer is at stake. It is not possible to remove from the register address details already supplied to the CRO.

Business name
Where a company uses a business name that is different from its company name, the business name must be registered by that company with the Irish Registrar of Business Names at the CRO.

Setting up a branch
Any foreign limited liability company trading in Ireland that has the appearance of permanency, an independent Irish management structure, the ability to negotiate contracts with third parties and a reasonable degree of financial independence is considered a branch under Irish company law. There are certain procedures set down for the registration of branches in Ireland involving the submission and authentication of the memorandum and articles of association of that company and, in certain situations, the filing of annual accounts for that entity.

In some cases, it may make sense from a tax perspective to establish a foreign branch in Ireland, rather than incorporate a separate legal entity. If trading losses are likely to arise following the initial establishment in Ireland, such losses may be capable of being offset against the profits of the parent company in the parent company’s home state. If it is envisaged that the operations in Ireland would continue to be loss-making, then a branch may be preferable until such time as the operation becomes profitable. The most advantageous structure will only be identified after careful consideration of the proposed business, its relationship with the business of the foreign parent company and the projections for the profitability of the business in the future.

Place of business registrations
Under the 2014 Act, place of business registrations are no longer required or permitted in Ireland.
Taxation
Tax benefits of doing business in Ireland

The primary benefit, from a tax perspective, of doing business in Ireland is Ireland’s standard corporation tax rate of 12.5%. In a 2010 survey published in the IMD World Competitiveness Yearbook of key measures influencing FDI, Ireland ranked first for corporate taxes. The 12.5% rate applies to active profits. It has been approved by the EU, has not been challenged under the OECD base erosion and profit shifting project and is not dependent on negotiating or securing incentives, rulings or other tax holidays.

In recent years the introduction of an attractive holding company regime, the availability of improved credits for research and development expenditure and most recently the introduction of tax relief for the acquisition costs of IP and other intangibles, has greatly enhanced Ireland’s attractiveness from a tax perspective. The Irish government has also repeatedly reaffirmed its commitment to the 12.5% rate of corporation tax and an unrelenting willingness to further enhance the Irish tax system to attract further inward investment. The following recent changes to the Irish tax system emphasise this ongoing commitment:

- Dividends received by an Irish holding company from EU resident companies, companies resident in jurisdictions which have a tax treaty with Ireland (“Treaty Countries”) and companies resident in countries which have entered into certain forms of exchange of information treaty with Ireland are taxable at the rate of 12.5% (rather than 25%). Since 2010, the 12.5% rate now also applies to dividends received from subsidiaries located in non-Treaty Countries, where the shares of the subsidiary (or its ultimate 75% parent) are traded on a recognised stock exchange. In both cases the lower rate will only apply where dividends are paid out of trading profits of the subsidiary.
- The introduction of a relief for the acquisition of intellectual property and other intangibles in 2009 allows capital expenditure on intangibles to be amortised or depreciated against taxable income derived from such intangibles.
- The R&D tax credit regime (see below) was further enhanced in 2008 by introducing increased flexibility for the use of R&D tax credits. Such credits can now be offset against profits from the preceding accounting period, and if an excess still remains two years after the credit arose, can be repaid to the taxpayer. Since 2012, credits can also be surrendered to key employees engaged in R&D activities in certain circumstances. Historically, credits were only available in respect of spending on R&D in excess of 2003 spending (the “base year”). This base year restriction has been removed and from 2015 all spending on R&D will be available as a credit.
- A number of domestic exemptions (including dividend withholding tax and interest withholding tax) are available not only to persons resident in Treaty Countries, but also to persons resident in jurisdictions which have signed a double taxation treaty with Ireland and that treaty has not yet been fully ratified.
- Ireland imposes a withholding tax on patent royalties. A domestic exemption from patent royalty withholding tax was introduced in 2010 in respect of royalty payments made to companies resident in the EU and Treaty Countries. Also, pursuant to an administrative practice introduced in 2010, in certain circumstances, the payment of patent royalties by an Irish company in respect of a “foreign patent” to any non-resident company (irrespective of its location) can now be made free of withholding tax, subject to prior approval of the Irish Revenue Commissioners (Revenue).
- Measures to facilitate the development of Islamic finance in Ireland were introduced in 2010. Under these provisions, the tax treatment applicable to conventional finance transactions will apply in the same manner to Sharia compliant deposits, loans and bonds.
- The Special Assignee Relief Programme (“SARP”) allows certain executives who are assigned to work in Ireland by a company incorporated and tax resident in an EU or Treaty Country (as set out on page 20) a reduction on the taxable income, profits or gains liable to Irish tax which they receive from that company or a related company.
Activities that qualify for the 12.5% rate

The Irish corporation tax regime characterises income into two streams, with all trading income (broadly equivalent to active income) taxable at 12.5% and all non-trading income (equivalent to passive income) taxable at 25%.

Practically all active business pursuits will qualify for the 12.5% rate. The 12.5% rate is available to all industries and sectors, making Ireland attractive throughout all business sectors. In most cases the 12.5% rate will be available, provided the activity conducted in Ireland comprises the “carrying on of a trade” for tax purposes. Since the introduction of the 12.5% rate, it is clear that the latest generation of inward investors in Ireland include investors from industry sectors which may not have traditionally considered Ireland as a potential low-tax platform. The objective underpinning most investments is to avail of the possibilities presented to unbundle the traditional value chain and locate appropriate profit generating functions in Ireland.

Examples of activities in the traditional value chain which are capable of being unbundled and carried on in Ireland include:

- management activities (for example, legal, accounting, human resources, finance and reporting etc);
- financial activities (for example, cash management, banking, insurance and risk management);
- e-business (for example, CRM, procurement and distribution, supply chain management, marketing and selling);
- technical activities (for example, technical support, data management, security);
- research and/or development activities;
- ownership and exploitation of intellectual property; and
- distribution activities.

Ireland operates a self-assessment system for various taxes, including corporation tax. However, in certain circumstances, a taxpayer can request an opinion from Revenue on the tax consequences of a particular transaction in advance of the transaction taking place. Revenue have an established process where they will give an opinion as to a taxpayer’s entitlement to the 12.5% rate. Opinions given by Revenue are not legally binding and are based solely on the facts presented to them. It is open to Revenue officials to review the position taken in an opinion when a transaction is complete and all the facts are then known.
Why choose Ireland?

Tax legislation throughout the globe applicable to international business is becoming more complex and sophisticated each year. In particular, it is becoming increasingly difficult for multinational companies to preserve the tax advantages of locating in a low-tax country. In order to be attractive to the international business community, therefore, a low-tax jurisdiction must be able to offer more than just a low rate of tax. It is for this reason that Ireland is a particularly attractive location for multinationals. For example, the decision concerning the choice of locations for international businesses often turns on the perceived advantages and disadvantages between tax havens and onshore low-tax locations such as Ireland. The obvious advantage of a tax haven is the absence of any local corporation tax on profits. The obvious disadvantage of a tax haven is the absence of a tax treaty network. The less obvious disadvantages of establishing in a tax haven include:

- constraints on creating the necessary economic infrastructure to which value and ultimately profits can justifiably be attributed; and
- the general drive at EU and OECD level against harmful tax competition and tax havens in particular.

In contrast, Ireland combines the benefits of:

- an extensive tax treaty network;
- a low corporation tax environment which does not breach EU or OECD harmful tax competition criteria;
- the regulatory and economic infrastructure of a highly developed OECD jurisdiction;
- the benefits of EU membership (for example, Irish regulatory approval generally suffices as a European passport for regulated goods and services throughout the EU);
- the physical and people infrastructure to enable the establishment of profit generating centres defensible by reference to functions, risks and tangible assets of the Irish operation; and
- the physical proximity to Europe, offering a real gateway to the EU market.

Apart from the low rate of corporation tax, other key tax benefits of locating in Ireland include:

- no withholding tax on interest payments to EU/Treaty Countries;
- wide exemptions from withholding tax on dividend payments;
- no withholding tax on royalties to EU/Treaty Countries, and in certain cases to non-EU/non-Treaty Countries;
- an extensive and expanding double tax treaty network;
- a comprehensive unilateral foreign tax credit system;
- no controlled foreign corporation rules;
- no specific code of thin capitalisation rules;
- no capital gains tax exit charge to EU/Treaty Countries;
- an exemption from capital gains tax in respect of the disposal of shareholdings in qualifying companies;
- no companies registration taxes (capital duty);
- a refundable tax credit of 25% for incremental research and development expenditure;
- a corporate tax relief for the acquisition cost of IP and other intangibles; and
- no custom duties on Irish goods on their importation into other parts of the EU.
Negotiations for a double tax treaty with Turkmenistan have concluded and that treaty is expected to be signed shortly. Negotiations for agreements with Azerbaijan, Ghana, Jordan and Kazakhstan are in progress. The Irish Revenue Commissioners intend to initiate negotiations for further new agreements with other countries in the near future.

General scope of Irish corporation tax

Charge to tax and residence
Companies which are resident in Ireland for tax purposes are subject to corporation tax on worldwide income and gains. A non-resident company is chargeable to corporation tax on profits arising from a business conducted through a branch or agency in Ireland.

In determining whether an Irish incorporated company is tax resident in Ireland, one of two rules will apply. Which rule applies depends on when the company was incorporated.

Companies incorporated in Ireland before 2015
A company that was incorporated in Ireland on or before 31 December 2014 will be regarded as tax resident in Ireland, unless:

(a) the company or a related company is carrying on a trade in Ireland, and either:

(i) the company is ultimately controlled by tax residents of an EU Member State or a Treaty Country; or

(ii) the company or a related company is quoted on a recognised stock exchange of an EU Member State or a Treaty Country; or

* Treaties with Botswana and Ethiopia have been signed, but have not yet been fully ratified.
(b) the company is treated as resident in a country by virtue of a double tax treaty entered into between a Treaty Country and Ireland.

For those companies that fall under the exceptions at (a) or (b), tax residence is determined by reference to the place where the central management and control of the company abides.

In practice, and in the absence of evidence to the contrary, the courts generally place considerable emphasis on meetings of the board of directors in determining who exercises the central management and control of a company. The reason for this is that, in general, the business of companies is managed by their directors and such management is normally conducted at meetings of the board of directors. If meetings of the directors who actually manage the company’s business in this manner are held in Ireland, the company would generally be regarded as centrally managed and controlled in Ireland.

In a limited number of cases, an Irish company incorporated before 2015 may have its place of central management and control in an EU Member State or a Treaty Country that does not recognise the company as a resident of that jurisdiction. In such cases, the company will be regarded as resident in Ireland for tax purposes.

From 1 January 2021 (or earlier if certain anti-avoidance provisions apply), the residence of all companies incorporated in Ireland (including those incorporated before 2015) will be determined according to the new rule.

Companies incorporated in Ireland from 2015 (the “new rule”)
Companies incorporated in Ireland on or after 1 January 2015 will be regarded as resident in Ireland, unless the company is treated as resident elsewhere under the terms of a double tax treaty entered into between a Treaty Country and Ireland. From 1 January 2021, this rule will apply to all Irish incorporated companies.

For companies not incorporated in Ireland, Irish tax residence is determined by reference to the place where the central management and control abides.

In order to benefit from Ireland’s tax treaties, companies must, in general, be residents of Ireland within the meaning of the relevant treaty.

Computation of taxable income
Ireland operates a self-assessment system for tax purposes. In general, the trading profits of a company are computed in accordance with general accounting principles. It is important, however, to take account of specific statutory provisions which may depart from the general accounting treatment. For example, only expenses which are incurred wholly and exclusively for the purposes of trading activities are allowable as a deduction in calculating the profits of a company for tax purposes. Also, there are specific provisions relating to the deductibility of entertainment expenses, motor vehicle expenses, pre-trading expenses, provisions, interest and royalty payments. Dividends paid by an Irish resident company are not deductible. Such dividends are regarded as “franked investment income” and therefore not taxable in the hands of another Irish resident company. There are detailed rules relating to the deductibility of interest payments in place. Subject to certain limitations, where interest is paid wholly and exclusively for the purposes of a trade by an Irish company, such interest will be deductible. Interest may also be deductible in other limited circumstances where the loan is used for investment in other companies.

Tax depreciation and loss relief
Tax losses and tax depreciation are deductible in accordance with special rules. In general, the tax losses of a company which forms part of a tax group can be offset against taxable profits of another group company. For these purposes a group can include EU resident companies. Losses may also be surrendered from EU subsidiaries and between branches of EU companies and Irish subsidiaries in limited circumstances. It should be noted that the concept of a group consolidated tax return or tax unity does not exist in Ireland.

Refundable research and development tax credit
A refundable corporation tax credit of 25% for incremental qualifying R&D expenditure is available in Ireland. This tax credit is available in respect of qualifying R&D expenditure undertaken within the EEA. This R&D tax credit is in addition to the existing deduction and capital allowances that may be available for R&D expenditure. The R&D tax credit is allowed against a company’s corporation tax liability for the year in which it is incurred. Excess R&D tax credits can be carried back against a company’s corporation tax liability in the accounting period preceding the accounting period in which the qualifying R&D expenditure is incurred. Any excess R&D tax credit can also be carried forward against future corporation tax profits and, importantly, can now be claimed back as a refund from Revenue where it is not possible to utilise the credit in the two years following the accounting period in which the R&D tax credit arises. It is also possible to surrender R&D tax credits to key employees who are engaged substantially in R&D activities for the company subject to certain restrictions.

Tax relief for acquisition costs of IP and other intangibles
Capital expenditure incurred after 7 May 2009 on “intangible assets” which are acquired for the purposes of a trade can be offset against taxable income for corporate tax purposes. The tax relief available reflects the standard accounting treatment of the intangible assets and is based on the amount charged to the profit and loss account in respect of the amortisation or depreciation of the relevant intangible asset. Alternatively, the taxpayer can opt to claim relief over 15 years at a rate of 7% for the first 14 years with the remaining 2% of the relief claimed in the final year. Any unutilised relief may be carried forward indefinitely for offset against future income from the IP trade. The definition of intangibles for the purposes of the relief has been very widely drafted and includes goodwill directly attributable to intangibles.

The regime specifically provides that where intangible assets are acquired from a group company in circumstances where such transferor would be entitled to Irish capital gains tax group relief, the acquiring company will be able to claim the relief on the assets acquired only if both it and the transferring company elect to opt out of the group relief provisions.

Relief is not available for capital expenditure on intangible assets if another relief is available or where the expenditure incurred exceeds the amount that would be payable between independent parties. Relief is also not available in respect of any expenditure incurred as part of a tax avoidance arrangement. The intangible asset must continue to be used in a trade for five years to avoid triggering a clawback of the relief obtained.
Attractive holding company and headquarter regime

Ireland offers an attractive tax regime for holding companies and this is reflected in the number of companies choosing to relocate their headquarters to Ireland. The two main features of this regime are (a) a ‘substantial shareholdings’ exemption from Irish tax on the sale of subsidiaries, and (b) an advantageous treatment of foreign dividend income.

Exemption from Irish tax on sale of subsidiaries

Ireland’s ‘substantial shareholdings’ exemption relieves holding companies from Irish capital gains taxation on disposals of subsidiaries. Two main conditions apply: (a) the subsidiary must be resident in the EU or a Treaty Country; and (b) a minimum 5% shareholding must be held for a continuous period of at least 12 months.

Advantageous treatment of foreign dividend income

Generally, Irish holding companies can receive dividends from their foreign subsidiaries on an effective tax-free basis in Ireland (or with a very low effective rate of Irish tax). This is due to a combination of Ireland’s low corporation tax rate for most dividends and the availability of Irish credit relief for foreign taxes. The 12.5% corporation tax rate applies to dividend income received by an Irish company from its foreign subsidiaries in many cases, including where: (a) the subsidiaries are tax resident in the EU, a Treaty Country or a country which has ratified the Convention on Mutual Assistance in Tax Matters with Ireland, or the subsidiary (or its ultimate 75% parent) is quoted on a recognised stock exchange in another EU member state or Treaty Country; and (b) those dividends are paid out of ‘trading’ profits of the foreign subsidiaries. If the dividends are partially paid out of non-trading profits, then the 12.5% still applies once (broadly speaking) at least 75% of the profits are trading profits. A higher rate of 25% applies to other dividend income.

However, foreign withholding taxes and (once a 5% shareholding is held) foreign underlying taxes may be credited (or set off) against this Irish tax liability. Recent changes introduced by the Finance Act 2013 ensure that additional tax will not arise on dividends received from companies resident in EU/EEA jurisdictions which have a higher nominal rate of tax than the applicable Irish corporate tax rate. Onshore dividend mixing is also permitted so that excess tax credits can be pooled against other dividend income sources. Typically, sufficient foreign taxes are payable to fully offset the 12.5% (or, as the case may be, the 25%) Irish tax due. Where this is the case, no Irish tax is payable on such dividend income.

Foreign dividends received on portfolio shareholdings (that is a holding that represents less than 5% of the share capital and voting rights) by Irish dealers in securities are now completely exempt from Irish corporation tax.

Other taxes

Capital gains tax

Companies resident in Ireland for tax purposes are subject to corporation tax on their gains. Non-resident companies are chargeable to capital gains tax on disposals of certain specified assets (for example, real estate situated in Ireland). The current rate of capital gains tax is 33%. Taxable gains are calculated by deducting from the sale proceeds the costs incurred on acquiring the assets. There are significant reliefs from capital gains tax on the transfer of assets intra group and in merger/reconstruction situations.

As outlined above, the disposal of shares in a subsidiary company by an Irish holding company is, in certain circumstances, exempt from Irish capital gains tax.

Value Added Tax ("VAT")

VAT operates as a turnover tax on all relevant supplies up to a point of final consumption or deemed consumption. This means that a taxable business must account for relevant VAT liabilities in respect of its Irish based taxable turnover but has the right to claim a deduction for VAT incurred on its own purchases, acquisitions and importations in respect of which Irish VAT is borne.

Ireland’s VAT regime is dictated by EU legislation with the result that Ireland’s VAT system is broadly in line with the pan-European harmonised system. The current rates of VAT are 0%, 4.8%, 5.2%, 9%, 13.5% and 23%. The standard rate of 23% is applicable unless one of the other rates is specified.

In general, VAT applies on all imports of goods from outside of the EU, the supply of goods and services within Ireland and to services received in Ireland from suppliers outside Ireland. Goods exported to businesses situated elsewhere in the European Community and to businesses or individuals situated outside the European Community generally attract the 0% rate of VAT. Most categories of services supplied to customers located outside of Ireland may not be chargeable to Irish VAT as the place of supply is deemed to be outside of Ireland.

Ireland operates a special VAT incentive for exporters of goods. Entities located in Ireland that supply in excess of 75% of their products to other EU locations or export to non-EU jurisdictions may qualify for authorisation to purchase most goods and services at the 0% rate of VAT. This can provide a substantial cash flow advantage for companies establishing their Europe Middle East and Africa ("EMEA") region operations in Ireland.
Stamp duty/capital duty
Stamp duty may arise on written instruments that are executed in Ireland or written instruments relating to Irish property. The rate of stamp duty varies depending on the nature of the underlying assets. Generally, the transfer of shares attracts a 1% rate of stamp duty, whilst transfers of commercial land and buildings attracts stamp duty of up to 2%. Transfers of intellectual property rights are exempt from stamp duty. There are significant reliefs from stamp duty on the transfer of assets intra group and in merger and group reorganisation situations. No capital duty arises on the issue of shares by an Irish company.

Customs duties
Customs duties are essentially EU taxes charged on the importation of goods from non-EU countries. The EU operates a common system of customs duty. Applicable rates vary greatly depending on the class of goods in question. A number of classes of goods, including goods within the computer and IT sector, are liable to the 0% rate of duty. A number of reliefs exist including the ability to import goods for processing and onward exportation beyond the EU free of customs duties.

Payroll taxes
Employment income in Ireland is subject to a withholding tax known as the Pay As You Earn (“PAYE”) system. This PAYE system must be operated by employers and is effectively designed to equate the tax withheld by the employer with the final liability of the employee in respect of his/her employment income for the relevant tax year.

Pay Related Social Insurance (“PRSI”) is another payroll tax operated by employers. Unlike PAYE, however, PRSI is paid partly by the employer and partly by the employee. The employer’s contribution is generally 10.75% of the relevant employee’s salary, whilst employees generally pay 4% of their salary. Employees will also pay a universal social charge of 1.5%, 3.5%, 7% and 8% depending on the amount of income earned.

Transfer pricing
Transfer pricing (“TP”) legislation was introduced in May 2010, with effect for accounting periods beginning on or after 1 January 2011. Arrangements entered into prior to 1 July 2010 are excluded from the scope of the legislation under the grandfathering provision. The TP legislation formally adopts the OECD arm’s length principle. Where an arrangement between associated persons is otherwise than at arm’s length, an adjustment must be made where the pricing results in the trading profits of the Irish resident company being understated.

Taxation of employees and Special Assignee Relief Programme
The tax treatment of an individual for Irish tax purposes will depend on whether they are Irish resident, ordinarily resident and/or Irish domiciled.

A person is “resident” for the day if they are present in Ireland at any time during a day. In an ongoing situation, it is possible for an individual to spend up to 139 days in Ireland in a tax year without becoming Irish resident.

The legal concept of “domicile” and a definitive explanation of its meaning is beyond the scope of this Guide. However domicile could be broadly defined as a person’s natural home. Every individual is born with a domicile of origin. It is possible for a person to lose their domicile of origin and acquire a domicile of choice. Likewise, it is possible for an individual to lose their domicile of choice and revive their domicile of origin. Domicile is an important concept under Irish law as it is relevant not only for tax purposes but also for determining the rules of succession, discussed further overleaf.

Where an individual is resident, ordinarily resident and domiciled in Ireland, they will be taxable on their worldwide income and gains, regardless of their source.

If a person is resident but not domiciled in Ireland, then liability to income tax is limited to Irish source income, income from an employment contract in respect of which the duties of such employment are exercised in Ireland and worldwide income to the extent remitted to Ireland. The liability of a person to capital gains tax where the person is either resident or ordinarily resident but not domiciled in Ireland is limited to Irish source gains and worldwide gains to the extent remitted to Ireland. This is known as the “remittance basis of taxation”. From an administrative perspective, it is sufficient to rely on non-remittance and there is no formal requirement to elect.

From 2012, an employee assigned to work in Ireland by a company incorporated and tax resident in a Treaty Country or a country with which Ireland has a Tax Information Exchange Agreement may claim a deduction from their income tax. The relief, referred to as the Special Assignee Relief Programme (“SARP”), allows assignees to obtain a tax deduction of up to 30% on employment income, profits or gains (including stock options) liable to Irish tax in excess of €75,000. In addition, assignees may receive certain personal benefits (an annual flight to the assignee’s country of residence, school fees of up to €5,000 for each child) from the employer without incurring a liability to tax.

In order to be eligible for SARP, assignees must be employed by the foreign company for at least six months prior to arriving in Ireland, they must take up employment in Ireland with that company and/or an associated company for a minimum of 12 months and they must have been non-Irish resident for the five tax years preceding the year of arrival. The relief must be claimed by the employee, and the employer must certify that certain requirements for the relief have been satisfied.

Other reliefs are available for temporary assignees and secondees who are not resident in Ireland, under published Revenue statements of practice.

Capital acquisitions tax (“CAT”)
It is important for any non-domiciled person considering moving to Ireland to note the potential exposure to CAT.

CAT is the generic name for the tax imposed on gifts and inheritances in Ireland, which is charged at 33%. CAT is a beneficiary based tax and is imposed on any Irish situate assets comprised in a gift or inheritance and where, at the time of the gift or inheritance, either the donor or beneficiary is resident in Ireland. The level of tax imposed will depend on the degree of relationship between the beneficiary and the disponent.

There is a statutory relief for non-domiciled individuals. They will not be deemed to be resident for CAT purposes unless they have been resident for five consecutive tax years at the relevant time. Where a non-domiciled Irish resident has been resident in Ireland for five consecutive years that person will be within the Irish CAT charge on their worldwide estates, as will any trusts of which they are the settlor.
Employment and Labour Law
Irish employment law has been considerably influenced by Ireland’s membership of the EU, with most Irish employment legislation now based on EU Directives.

Employee rights arising at commencement and during the course of employment

What information must be provided?
Each employee is entitled to a written statement of his or her terms and conditions of employment. An employee must also receive written details of the procedure which will be followed if the employee is going to be dismissed. An employee is also entitled to written statements showing the gross wages payable and the nature and amount of deductions applied.

Is there a minimum wage?
All employees over the age of 18 are entitled to the national minimum hourly rate of pay unless they fall into a category to which a sub-minimum hourly rate of pay applies. Sub-minimum rates apply to employees under the age of 18, job entrants who enter employment for the first time after the age of 18 and trainees.

What about restrictions on working time?
The maximum average hours that an employee may work is 48 hours per week, not including rest or lunch breaks. Employees are entitled to rest periods of at least 11 consecutive hours in every 24-hour period and must have at least one weekly rest period of 24 consecutive hours. This rest period must include a Sunday unless the employer specifically provides otherwise in the contract of employment. There are significant exceptions to the rules on working time for various categories of workers.

Is there employment equality legislation?
Discrimination on the following grounds is prohibited regarding both terms and conditions of, and access to, employment: gender, civil status, family status, sexual orientation, religious belief, age, disability, membership of the Traveller community and race which includes nationality, ethnic or national origin or colour.

What about part-time workers?
Discrimination against part-time employees is prohibited. Part-time workers must not be treated in a less favourable manner than comparable full-time workers solely because they work part-time, unless different treatment can be objectively justified.

What about fixed term workers?
Discrimination against employees on fixed term or specified purpose contracts is prohibited. Fixed term workers must not be treated in a less favourable manner than comparable permanent employees unless such difference in treatment can be objectively justified.

What about agency workers?
Agency workers who are temporarily assigned by an employment agency to work for and under the direction and supervision of a hirer, are entitled during their assignment to the same basic employment conditions, including basic pay, overtime etc, as if they were directly employed by the hirer. However, this does not include sick pay or any entitlement to pension benefits.

What about the statutory leave entitlements?
Every full time employee is entitled to four weeks (20 days) paid annual leave each year. In addition to paid annual leave, employees are also entitled to maternity, parental, force majeure, carers’, adoptive and health and safety leave. With the exception of force majeure and health and safety leave, there is usually no obligation to pay an employee while he or she is on such types of leave, although you may choose to do as a matter of contract. Employees are also entitled to nine further paid leave days annually for public holidays (or payment in lieu of same, depending on the circumstances).

What is the position with health and safety?
There is a duty on employers to provide for the safety, health and welfare of employees. This includes obligations to provide a workplace that is safe so far as reasonably practicable, safe plant and machinery and suitable protective clothing or equipment. Employers are also obliged to prepare a ‘safety statement’. This is a report setting out how employers intend to secure the safety, health and welfare of their employees in the workplace and to provide for safety representatives chosen from employees.

Must employers pay sick pay?
Employers are not obliged to provide sick pay but, if a sick pay scheme is in place, all employees must generally be entitled to it equally.
Is there protection for whistleblowers?
Ireland recently introduced whistleblowing legislation in the form of the Protected Disclosures Act 2014 ("PDA"). The PDA covers protected disclosures that are made by "workers" (public and private sector), which includes employees, contractors, agency staff, former employees and trainees. The PDA protects an employee from penalisation or dismissal on the grounds of having made a protected disclosure. An employee may recover up to five years’ gross remuneration as compensation.

Employee rights arising on termination

How much notice must be given to terminate an employee?
Where either an employee or an employer wishes to end a contract of employment, minimum terms of notice apply where there has been continuous service for at least 13 weeks. The notice period to be given by an employer depends on the employee’s length of service. It varies from one week, applicable where an employee has been employed for up to two years, to eight weeks’ notice, applicable where an employee has been employed for 15 years and upwards. Employees, on the other hand, are only obliged to give notice of one week, irrespective of their length of service. These are, of course, only the minimum prescribed periods and the parties may agree a longer period of notice by contract.

Are all employees entitled to redundancy?
An employee is entitled to a redundancy payment where he or she has worked continuously for two years or more and is either dismissed by reason of redundancy or is laid off or kept on short time for a given period of time. Statutory entitlement is two weeks per year of service plus one bonus week. Employers often make an ex gratia payment along with the statutory payment but are not obliged by law to do so. Certain formal procedures must be observed. Employees must be given at least two weeks’ notice of redundancy. Certain additional rules and consultation requirements apply where an employer is considering a number of redundancies at the same time.

Is there unfair dismissal legislation?
Where an employee is unfairly dismissed, he or she has a right to compensation, reinstatement or re-engagement under the Unfair Dismissals Acts. Unfair dismissal legislation applies to those employees who have at least one year’s continuous service. The legislation also covers instances where an employee is constructively dismissed. This may arise where the employer’s behaviour was such that the employee was forced to leave or the employer unilaterally implemented a material variation of an employee’s contract of employment without his or her consent.

Employers must apply fair procedures when dismissing an employee (for example, warnings must be given except in circumstances amounting to gross misconduct). The employee must be heard and a fair and proper investigation into the circumstances leading to the dismissal must be carried out.

Do rules apply on the transfer of employees?
Detailed rules apply regarding the treatment of employees where a business (or assets pertaining to the business) is being transferred from one employer to another. The rules do not apply to a share transfer. In essence, the obligations the original employer had towards his employees will be taken over by the new employer. This includes rights arising from the contract of employment, collective agreements and legislation. Both the previous and new employer are obliged to inform their employees’ representatives of the reasons for the transfer, the implications of the transfer, and the measures envisaged to be taken in relation to the affected employees, in good time before the transfer is carried out. Where there are measures envisaged, there is a requirement to consult.

Other employment matters

What about industrial relations?
While employees in Ireland have a right to join a trade union, employers are not obliged to recognise trade unions for collective bargaining purposes (although where collective bargaining does not take place, employers may be obliged in certain circumstances to deal indirectly with unions under the auspices of the Labour Relations Commission or the Labour Court). Depending on the number of employees an employer has in EU Member States, an employer may be required to establish a European Works Council facilitating employee access to management information relating to transnational questions which significantly affect employees’ interests, though management may withhold information that it claims is commercially sensitive, and to consult with management on such questions. EU law requires the establishment of workers’ councils by larger employers, who employ at least 1,000 employees in the EU and which have undertakings in two or more Member States of the EU which employ at least 150 employees each. Again depending on numbers, an employer may also be required to establish a local works council which will also facilitate access to information and consultation. However, such local works councils are relatively powerless in comparison to works councils in some European civil law jurisdictions. Irish employees do not have any right to veto any decisions of the employer.

Employment permits for non-EEA nationals?
Most non-EEA nationals require an employment permit to work in Ireland. As a result, employers should always confirm a prospective employee’s entitlement to work in Ireland prior to commencement of employment. There are various types of employment permits which are available namely: General Employment Permit, Critical Skills Employment Permit, Intra-Company Transfer Employment Permit, a Dependent, Partner and Spouse Permit, Exchange Agreement Employment Permit, Sports and Cultural Employment Permit, Internship Employment Permit, Reactivation Employment Permit and Contract for Services Employment Permit. The preferred permit in each case will depend on the particular circumstances. There is usually a fee for permit applications (in most cases €1,000 for a two year permit) and applications can take several months to process. In some cases, for example General Employment Permits, advertising of the vacancy is required prior to submitting the application. Therefore, applications should be prepared well in advance of the anticipated start date.

Employees who work under an employment permit are entitled to the protection of employment legislation in Ireland in the same way as Irish or EU nationals.

There are severe penalties for employing a non-EEA national without the appropriate employment permit. If found guilty of such an offence, fines up to a maximum of €250,000 can be imposed on the employer and/or imprisonment up to a maximum of ten years.

Employee benefits and pensions
An employer may wish to provide its employees with employee benefits such as life insurance, pensions, private health insurance, sick pay and share incentive schemes. There is no legal obligation in Ireland to
provide any of these benefits, save for pensions, where it is obligatory for all employers to offer access to a Personal Retirement Savings Account ("PRSA") to all employees, unless each employee has access to an occupational pension scheme within six months of being employed. There is no obligation on an employer to contribute to a PRSA on behalf of an employee.

PRSA products are available from life assurance companies, banks and other investment firms. Each product has to be approved by both the Irish Pensions Authority and the Irish Revenue Commissioners before they can be sold.

An occupational pension scheme can either be on a defined benefit or a defined contribution basis. Most larger Irish employers provide one or other such scheme (although new schemes are usually established on a defined contribution basis), with varying contribution levels and eligibility criteria.

Cross-border pension schemes

Under current cross-border pension schemes legislation, Irish employers are able to establish arrangements (or adapt existing arrangements) to permit inclusion of employees of subsidiary companies or businesses established in other EU Member States which have also implemented the EU Pensions Directive and which will allow Irish employers (and employees) to make contributions on a tax exempt basis to a pension scheme established in another EU Member State. Foreign employers established in other EU Member States are also able to make contributions to pension schemes established in Ireland.

Irish-based pension schemes that wish to operate across EU borders (that is, to accept contributions in respect of members located in other EU Member States) must obtain prior authorisation from the Irish Pensions Authority. Trustees of Irish-based schemes are required to furnish information to the Irish Pensions Authority in relation to cross-border employers. Detailed notification requirements are now prescribed in regulations. The regulations also provide details of the regulatory requirements for approval of cross-border arrangements.

The legislation allows multinational employers with operations in Europe to establish a company or branch in Ireland which in turn would sponsor an occupational pension arrangement. That arrangement could then seek authorisation from the Irish Pensions Authority to accept contributions from overseas employers located in other EU Member States.
Real Estate, Planning and Environmental Law, Construction and Energy
Real estate
Most inward investment projects will involve the acquisition of some interest in Irish real estate, with associated regulatory issues including applications for planning permission, building control compliance and environmental licences or permits also likely to arise. There are generally no restrictions on foreign individuals or corporations purchasing or leasing land.

Depending on the nature of the project, it may be necessary to retain the services of a property consultant (who can assist with the identification and valuation of any proposed site or property), an architect/engineer to carry out structural surveys or to design a facility and environmental consultants who may be needed to carry out environmental assessments. It is also important for purchasers to liaise with local authorities and utility companies to ensure that there is adequate infrastructure and that there will be adequate utilities for the intended project.

What is the process for the purchase of commercial real estate?
The purchase of real estate in Ireland is dealt with by real estate lawyers who investigate the vendor’s title and ability to sell the property, carry out searches of the local authority registers and advise as to the necessary structural surveys and environmental assessments required. Having agreed the purchase price with the vendor or his agent and, if required, paid a booking deposit, the purchase of commercial real estate involves agreeing the terms of a contract for sale of the property, the payment of a deposit (typically 10% of the overall purchase price) upon signing of the contract, followed some weeks later by the execution of the deeds of transfer and payment of the balance purchase monies. The purchase of property can take a number of months from the date of an initial offer to formal completion.

Real estate investment vehicles
The investment vehicle used for acquiring and holding Irish real estate depends on the profile of the investor. International investors use any one of a broad range of structures depending on their tax, reporting and corporate structures, including:
- Corporate vehicles;
- Unit trusts;
- Qualifying investor funds ("QIFs");
- Qualifying investor alternative investment funds ("QIAIFs");
- Co-ownerships;
- Partnerships;
- Limited partnerships;
- Investment limited partnerships;
- Real estate investment trusts ("REITs").

The use of QIFs and QIAIFs has increased in recent years. A framework for REITs was introduced into Irish law by the Finance Act 2013. REITs are an internationally recognised tax efficient model for real estate investment that is attractive to institutional investors, private equity and pension funds. REITs also enable smaller retail investors to access returns from prime real estate that could otherwise be beyond their reach.

What is the process for the leasing of commercial real estate?
As an alternative to purchasing premises, businesses often opt to lease commercial real estate, with the flexibility of negotiating a term which aligns to their business plans. While five year leases are commonplace for small office space, tenants of larger spaces tend to take leases for terms ranging from ten to 20 years. There is no automatic right to “break” the lease. However, it may be possible to negotiate an entitlement to terminate the lease, known as a “break clause”, normally midway through the term. Landlords may seek payment of a compensatory penalty for exercising the break clause. Other inducements which may be offered to prospective tenants include rent free periods, capital contributions and fit out allowances.

Rent reviews normally occur at five yearly intervals. Such provisions are a matter for negotiation between the landlord and the tenant. In Ireland, up until 28 February 2010, rent reviews were “upwards only”, resulting in the rent either increasing if the market rate was higher or remaining the same when the market rate was lower. However, since 28 February 2010 the rent review provision in any new lease is construed as providing that on review the rent may be revised either upwards or downwards, meaning the rent payable can decrease on review. This applies only in respect of leases created since that date and not pre-existing leases.

The ban on upwards only rent review clauses has resulted in some alternative approaches to rent review, including turnover rents, stepped rents, index-linked rents and capped market rents that cannot increase/decrease beyond a set percentage.

Leases in Ireland are usually on a “full repairing and insuring” basis, which means the tenant is liable for the full cost of repairing and insuring the property.

Details of every commercial lease in Ireland entered into on or after 3 April 2012 and rent reviews under those leases are recorded on a public register called the Commercial Leases Register. Tenants are required by law to submit information about the commercial terms of such leases, any rent reviews and any assignment or termination of their interest in the leases. The Commercial Leases Register provides transparency in the market.
What are the property taxation issues?
Stamp duty is payable by the purchaser of commercial real estate on the purchase price at the rate of 2%. On the grant of a lease the 2% rate applies to any premium paid by the tenant for the grant of the lease and the tenant must also pay stamp duty at a rate of 1% on the annual rent for an occupational lease not exceeding 35 years and higher rates for longer leases.

The amount of Value Added Tax ("VAT") recovery available is a material factor in considering the VAT implications of leasing or purchasing property in Ireland. A new VAT regime in respect of property commenced on 1 July 2008, including the introduction of a Capital Goods Scheme into Ireland. Specialist VAT advice is generally recommended for acquisition of an interest in property in Ireland.

If acquiring a freehold interest in property, the age of the building, its history in terms of occupation and development and the VAT status of any lettings are all factors which may go to determining whether VAT is payable on acquisition of a freehold interest. Even if VAT exempt, both parties may jointly opt to charge VAT on the transaction, currently at the rate of 13.5%.

All leases granted after 1 July 2008 may attract VAT on the rental payments, currently at the rate of 23%. The landlord has the option whether or not to charge VAT on the rent.

Rates and water charges
Rates are a form of local taxation which apply to commercial property only. Local authorities in Ireland raise rates on the basis of property valuations (rateable valuations) provided to them on request by the Valuation Office which is the State property valuation office. The amount payable (which can be substantial) is paid to the local authority. Rates are normally increased annually in line with the annual rate of inflation.

In addition, water charges are payable if water is being supplied for use by business, trade or manufacture. At present businesses can either pay a flat rate or have their water usage monitored using a meter, but in the future all commercial premises will be required to have a meter. Residential properties are subject to a separate Local Property Tax and water charges regime.

When is planning permission required?
Planning permission is required before land, structures or buildings can be developed, or before the existing use can be materially changed. Initial consultation with the local planning authority is recommended. Public notice must be given, after which an application for planning permission is submitted to the local planning authority. The planning application is made directly to the national Planning Board, an Bord Pleanala, for development that is regarded as 'strategic infrastructure'. It may also be necessary to prepare and submit an environmental impact statement with the planning application and/or a screening report for appropriate assessment or Natura Impact Statement.

The local planning authority may grant or refuse planning permission or grant permission subject to certain conditions (which is generally the case). Members of the public may object in writing before any decision is made and rights of appeal to the Planning Board exist. Generally speaking it can take eight weeks or more to obtain planning permission from the date of application. Once granted, it is subject to appeal to the Planning Board within one month of a local authority decision. The appeals process generally takes more than four months, with complex appeals on major projects (which often involve oral public hearings) lasting considerably longer. Planning permission generally has a life span of five years, unless the developer asks for a longer initial period and this is granted. The life span can be extended in certain circumstances upon application to the planning authority.

On completion of development the architects and (where appropriate) engineers are required to provide opinions/certificates on compliance with planning permission and building regulations. These documents are required as evidence of compliance on any subsequent sale or lease of the property.

For most works commenced on or after 1 March 2014, a statutory certificate of compliance with building regulations must be registered with the building control authority before a building or works may be opened, occupied or used.

Building Energy Rating Certificate
A Building Energy Rating ("BER") Certificate, which shows the energy performance, CO₂ emission and approximate running cost of a building, must be provided to any person expressing an interest in purchasing or leasing a building before they enter into a contract for purchase or lease. Each BER must be accompanied by an Advisory Report which will consist of recommendations to improve the energy performance of the building.

Environmental Consents/Permits
There are a number of environmental regulators in Ireland, including the Environmental Protection Agency of Ireland ("EPA") and local authorities. Depending on the nature of the project, the development may be regulated and licensed by the EPA or by another environmental regulator such as a local authority, Irish Water or Government Department. For example, in respect of certain facilities, an Industrial Emissions Licence ("IED licence") or an Integrated Pollution Prevention Control ("IPPC") Licence may be required. The IED and IPPC licensing regime takes an integrated approach covering for example, air, water, solid waste and noise pollution. If an IED or IPPC licence is not required, it may be necessary to apply to the local authority or Irish Water for a water discharge permit or an air emission licence. It is also obligatory to properly provide for the disposal of any waste produced by the project. Different regimes apply to the disposal of hazardous and non-hazardous waste.
Construction

Many large scale inward investment projects involve the construction of purpose built facilities on green field sites. Typically, this will involve the engagement of a design team to carry out either front end design/ preliminary design only or overall design. In addition, a construction contractor will need to be selected and engaged pursuant to a construction contract. The construction contract can either be a build only contract (ie, with no design input by the contractor) or a design and build contract whereby the contractor designs the entire project or develops the front end/preliminary design already undertaken by a design team. For more complicated builds, management contracting, mechanical and electrical and turnkey/engineer, procure, construction (EPC) forms of construction contracts can be used. The key feature of an EPC/turnkey contract is that there is a relatively onerous risk transfer to the contractor of price, time and quality.

Engagement of consultants

Generally, a manufacturer/inward investor will appoint its own design team/consultants, including an architect, quantity surveyor, structural engineer, mechanical and electrical engineer and a project manager (frequently the quantity surveyor). In some cases, a manufacturer/inward investor will have their own bespoke sophisticated suite of consultant contracts for use and they will prefer to contract directly with each member of the design team. It is also possible to contract directly with some of the consultants only, for example, the mechanical and electrical engineer and the project manager in the case of the construction of a manufacturing plant. The project manager will then enter into sub-consultancy contracts with the rest of the consultants and takes full responsibility for their co-ordination and delivery of agreed output. There is no recent “market” template consultant contract for use in the private sector in Ireland, but there are a number of standard terms and conditions which are considered “market” in this jurisdiction.

The project manager will usually have responsibility for conducting the tendering/procurement process with prospective contractors.

Engagement of the contractor

Most straightforward “build only” construction and civil engineering projects in Ireland are typically governed by the general conditions produced by either the Royal Institute of Architects of Ireland (“RIAI”) or Engineers Ireland. These general conditions are usually heavily amended by the parties to reflect what is currently acceptable in the market. These contracts can also be amended to become design and build contracts.

In the case of more complicated projects or mechanical and electrical contracts, for example, in the pharmaceutical, information technology and energy markets, there are a number of other types of contracts which are commonly used, for example:

(a) the FIDIC suite of contracts which includes a build only form of contract, a design and build mechanical and electrical contract and a turnkey/EPC contract (as amended);

(b) management contracts; and

(c) EPC/turnkey contracts.

International companies frequently use their own bespoke subcontracts for key specialist elements.

Energy procurement

Priority should be given to ensuring that your business has the most cost effective and flexible energy supply arrangements in place. It will be necessary to liaise with the electricity and gas network operators to put in place contracts to connect your business premises to the electricity and gas grids, and to put in place electricity and/or gas contracts. In addition, it is necessary to liaise with local authorities in relation to water and waste water connection and water supply.
Substantial efforts have been made at a political level to establish Ireland as the preferred location for e-commerce, technology and intellectual property-based industries and there has been heavy Government investment in the area.

The patent protection regime
Patent protection in Ireland will (a) last for a period of 20 years from the date of filing in the case of a full-term patent, and (b) last for a period of ten years from the date of filing in the case of a short-term patent, subject to the payment of renewal fees.

Although Irish patent legislation specifically excludes "computer programs" from patentability, this exclusion had been interpreted very narrowly. As with the European Patent Convention (see below), the Irish Patent Office has permitted computer software to be patented provided it meets the general criteria for patentability under the Patents Act 1992.

Ireland has ratified the European Patent Convention ("EPC") and the Patent Co-Operation Treaty ("PCT"). Patents can therefore be applied for through the PCT system, the EPC system, or through the Irish Patents Office. The EPC system enables applicants to secure patent rights in a number of European countries by way of filing a single application to the European Patent Office. When granted, this application results in a bundle of national patents in each of the countries which the applicant has designated. The PCT system operates in a similar manner to the EPC system, allowing for a single application designating as many member states as desired and resulting in the grant of a bundle of national patents.

In addition, Ireland has been a signatory to The International Convention for the Protection of Industrial Property (the "Paris Convention") since 1925, pursuant to which each Convention country must grant, as regards intellectual property rights, the same protection to nationals of all other Convention countries as it grants to its own nationals.

In what is the most significant development in patent law for decades, the European unitary patent will soon guarantee protection through a new single patent right for inventions in 25 countries across Europe, including Ireland. The regulations regarding the unitary patent entered into force on 20 January 2013 but are not applicable until the entry into force of the Agreement on a Unified Patent Court which must be ratified by 13 Member States, three of which must be France, Germany and the UK. In November 2014 the Irish Government announced that it will establish a local division of the Unified Patent Court in Ireland. However the adoption of the unitary patent system by Ireland is dependent on a successful national referendum which is expected to take place in 2016. If the referendum is passed and the Agreement is ratified by requisite Member States then the new system is likely to commence in 2017.

Copyright in Ireland
Irish copyright law is in line with the copyright laws of many other EU countries with provision for performers rights, rental and lending rights and database rights (see below). Irish law also specifically protects copyright in computer software, as a literary work. Moral rights are also provided for, in a similar manner to the UK.

There are no registration formalities in Ireland in order to obtain copyright protection. The statutory period of protection for most copyright works lasts, in the main, until the expiration of 70 years after the date of death of the author.

In addition to being a signatory to the Paris Convention (see above), Ireland is also a signatory to the Berne Convention for the Protection of Literary and Artistic Works, pursuant to which works originating in one Convention country are given the same protection in all other Convention countries as they grant to works of their own nationals.

Are databases protected in Ireland?
Yes. The EU Directive on the legal protection of databases has been implemented in Ireland. Irish law provides that copyright subsists in original databases, the period of protection lasting until 70 years after the death of the author, irrespective of the date on which the work is first lawfully made available to the public. Databases (irrespective of whether the database is a copyright work) are also protected where there has been a substantial investment in obtaining, verifying or presenting the contents of the database. The database right expires 15 years from the end of the calendar year in which the making of the database was completed.

Is there legislation on industrial designs?
Yes. Irish law gives effect to Directive 98/71/EC on the Legal Protection of Designs and to the Geneva Act of The Hague Agreement concerning the International Registration of Industrial Designs. Protection for registered designs lasts for a maximum period of 25 years, renewable at five-year intervals.

In addition, Ireland benefits from the introduction of the Registered Community Design Right and the Unregistered Community Design Right, which were introduced into Ireland in 2002. The Registered Community Design system offers a single unitary right covering all Member States of the EU. The substantive requirements for valid registration are that the design must be new and must have individual character. The total term of protection is 25 years, renewable at five year intervals.

The substantive requirements for protection are generally the same as for the Registered Community Design, except that in this case no registration is required. An unregistered Community Design Right exists for a period of three years from the date the design is first made available to the public within the EU in such a way that, in the normal course of business, the disclosure could reasonably have become known to the circles specialised in the sector concerned, operating within the EU.

In addition, Ireland has implemented the Directive on the Legal Protection of Topographies of Semiconductor Products (87/54/EEC), which affords protection to the design and the layout of the elements composing a semi-conductor product. The right to protection generally commences when the topography is first fixed or encoded and lasts for ten years.

Can we fully protect our Trade Marks in Ireland?
Yes. An owner of a trade mark, service mark or logo may seek protection under Irish statute by registering the mark/logo on the Irish Trade Marks Registry. A registration lasts for a period of ten years and can be renewed for further ten-year periods provided the renewal fee is paid.

Whilst statutory protection extends only to the jurisdiction of Ireland, Ireland is one of the EU Member States in which a Community Trade Mark (registered in the Office for Harmonisation of the Internal Market in Alicante, Spain), if registered, will be effective throughout the EU.
Also, Ireland has ratified the Madrid Protocol. This Protocol allows for a single application for a trade mark registration to be filed at the Trade Mark Registry of any country which is a party to the Protocol and to request that the application be extended to such other countries which are a party to the Protocol as the applicant may designate.

An international registration produces the same effects as an application for registration of the mark made in each of the countries designated by the applicant.

In addition to statutory protection, the goodwill in unregistered marks and logos can be protected by way of the common law tort of passing off.

**Confidential information and trade secrets?**

Other than the indirect protection afforded by data protection legislation, there is no statutory regulation regarding the disclosure of confidential information and trade secrets in Ireland. Confidential information and trade secrets can be protected by contractual provision or, in the absence of contractual provision, by an action in common law for breach of confidence.

---

**Irish legislation for e-commerce**

Ireland’s primary e-commerce legislation is found in the Electronic Commerce Act 2000 which implemented certain EU legislation into Irish law. The 2000 Act not only gives legal recognition and legal admissibility to electronic signatures but also to information in electronic form generally. Specifically it addresses electronic writing, electronic witnessing, electronic documents, electronic originals and electronic contracts. It also contains provisions dealing with the requirements for the retention and production of electronic information and provides default rules for determining when electronic communications are deemed to be sent and received. The 2000 Act also makes provision for the accreditation and supervision of certification service providers and has provisions dealing with their liability.

Further EU and Irish legislation needs to be considered by all businesses that sell goods or services to consumers ‘at a distance’, such as through the Internet, interactive digital television, mail order, telephone and fax. There is a regulatory regime for entities issuing electronic money and selling financial services. The Central Bank of Ireland is responsible for the authorisation and supervision of Electronic Money Institutions and other financial institutions.

**Data protection/privacy**

Ireland has a comprehensive legislative data protection regime derived from EU law. The principal legislation, the Data Protection Acts 1988 and 2003, set out a legal framework which specifies a number of data protection principles that must be complied with when personal data is processed. Additionally, certain conditions must be met in order for such processing to be “legitimate” (which conditions differ depending on whether the personal data in question is sensitive or non-sensitive in nature). A number of rights are conferred on data subjects to access personal data relating to them and to have incorrect or misleading personal data corrected, rectified or erased. Specific conditions apply to direct marketing, security, automated individual decision making processes and the control of transfers of personal data from Ireland outside of the EEA.
The European Commission has published a proposed Data Protection Framework for the EU which is intended to be enacted as a European Regulation in order to further harmonise data protection laws across the EU and to replace the existing data protection law in each Member State of the EU. The draft Regulation proposes a number of important and significant changes to the existing law. The European Commission hopes to finalise the new Regulation by the end of 2015, followed by a two-year implementation period.

The Communications (Retention of Data) Act 2011 requires “service providers” (persons engaged in the provision of a publicly available electronic communications services or a public communications network by means of a fixed line, mobile telephones or the Internet) to retain specific data for specified periods (two years for call data and one year for Internet-use data) and to make it available to the Irish police, Irish army and the Irish taxation authorities in specific circumstances, by way of a “disclosure request”.

Are there any “dual-use” controls?
The control of the export of “dual-use” items and military goods is governed by the Control of Exports Act 2008 and the Control of Exports (Dual Use Items) Order 2009, which gives effect to Council Regulation (EC) No. 428/2009 (the “Dual-Use Regulation”) setting up a community regime for the control of exports, transfer, brokering and transit of dual-use items. Significant changes to the Dual-Use Regulation were made in December 2014 through the implementation of Commission Delegated Regulation (EU) No. 1382/2014. These changes were enacted to take account of revisions made to the overarching international export control regimes in the 2011-2013 period and in this respect, some 400 revisions have been introduced to the Dual-Use Regulation, covering all categories (ie, categories 0 to 9) of the dual-use control list.

Dual-use goods and technologies are goods and technologies (including software) which are normally used for civilian purposes but which may have military applications. The legislation and requirements are complex and cover a wide range of common products produced by industries dealing with electronics, computers (including software), telecommunications and aerospace technologies.

The Export Licensing Unit is the division within the Irish Department of Jobs, Enterprise and Innovation which is responsible for managing controls on exports of dual-use items destined for countries to which trade sanctions apply.
Life Sciences Regulatory
Ireland has established itself as one of the leading locations for international companies in the life sciences sector, and is the number one European location for international investment. When considering establishing operations in Ireland, a few preliminary questions should be addressed.

**What authorisation is required to manufacture medicinal products in Ireland?**

Manufacturers of human and veterinary medicines in Ireland are required to hold a manufacturing authorisation granted by the Irish regulatory authority, the Health Products Regulatory Authority (the “HPRA”). The granting of a manufacturing authorisation in Ireland is principally governed by the Medicinal Products (Control of Manufacture) Regulations 2007, as amended, which transpose into Irish law elements of a number of EU Directives. Manufacturing includes activities such as total and partial manufacture, dividing up, packaging and repackaging, as well as importing medicinal products into Ireland from a country outside the European Economic Area (the “EEA”).

The HPRA will only grant a manufacturing authorisation if an applicant has at its disposal suitable and sufficient premises, equipment, facilities, staff, manufacturing operations and arrangements for quality control, record keeping, handling, storage and distribution. The applicant must have permanently and continuously at its disposal the services of at least one ‘Qualified Person’. A Qualified Person must have certain minimum qualifications defined in law and is responsible for ensuring that each release of medicinal products complies with the law and applicable regulatory requirements.

The HPRA recommends that any prospective manufacturer should meet with them for preliminary discussions prior to the commencement of any construction or ancillary works.

**What are the procedures to market medicinal products in Ireland and the EU?**

Subject to some minor exceptions, all medicinal products must be authorised before being marketed in Ireland. An application for a marketing authorisation (“MA”) must be made to the HPRA or the European Medicines Agency (“EMA”), where appropriate.

The marketing of medicinal products in Ireland is governed by the Medicinal Products (Control of Placing on the Market) Regulations 2007 as amended, which implement certain provisions of EU Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

An MA can be obtained using the following four procedures:

**National procedure**

An application for an MA is made directly to the HPRA. If the MA is granted it permits marketing of the medicinal product on the Irish market only.

**Mutual recognition procedure (“MRP”)**

The MRP is used when a medicinal product has been granted an MA in another EEA Member State. Under the MRP, an application can be made to the HPRA to mutually recognise an MA granted in another EEA Member State.

**Decentralised procedure (“DCP”)**

The DCP is used when a medicinal product does not yet have an MA in any EEA Member State, and the applicant wants to market its product in two or more member states. A ‘Reference Member State’ is chosen by the applicant. The regulatory authority of the Reference Member State then examines the application and prepares a preliminary assessment report which is sent to the regulatory authority of the other ‘Concerned Member States’ where the applicant wants to market its product.

**Centralised procedure**

This procedure is triggered in respect of the marketing of certain types of medicinal products, including all medicinal products for human use derived from biotechnology and other high-technology processes, as well as all human medicines containing a new active substance intended for the treatment of acquired immune deficiency syndrome, cancer, diabetes or new degenerative diseases and for all designated orphan medicines intended for the treatment of rare diseases. An application under this procedure must be made directly to the EMA and the MA granted is valid in all EEA Member States.

**What is the term of an MA?**

MAs granted by the HPRA generally last for five years and then need to be renewed. Applications for renewal must be made at least six months before the expiry of the existing MA. An MA will cease to be valid where the product is not placed on the market within three years of the MA being granted. It will also become invalid where the authorised product, having been initially placed on the market, is not present on the market for three consecutive years. Once renewed, an MA will generally last for an indefinite period.

**What are the post-marketing obligations of an MA holder?**

An MA holder must comply with pharmacovigilance requirements under Irish and EU law. Post-marketing pharmacovigilance obligations include:

- The MA holder must appoint a qualified person to maintain the system of pharmacovigilance, and must perform regular audits of the system, operate and monitor a risk management system in relation to medicinal products and maintain a pharmacovigilance system master file.
- The MA holder must also maintain a detailed record of any suspected adverse reactions and submit information to the Eudravigilance database within 15 days in the case of a serious suspected adverse reaction, or 90 days in the case of a non-serious suspected adverse reaction.
- The MA holder must submit periodic safety update reports to the HPRA or the EMA containing data relating to the risks and benefits of the product and the volume of sales of the product.
What is the basis for the labelling and packaging of medicinal products in Ireland?

Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC, provides the legal basis for the regulation of labels and package leaflets. This was transposed into Irish law by the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended.

What restrictions apply to advertising medicinal products in Ireland?

It is not permitted to advertise prescription-only medicines or controlled drugs to the public in Ireland. In addition, advertising unauthorised products is prohibited under the Medicinal Products (Control of Advertising) Regulations 2007 and the Irish Pharmaceutical Healthcare Association (“IPHA”) Code of Practice for the Pharmaceutical Industry.

Advertising of authorised products to healthcare professionals is permitted provided the advertisement includes the following information:

- essential information compatible with the SmPC;
- the name of the product and the list of the active ingredients;
- the classification of the product;
- one or more indications for use of the product;
- information regarding adverse reactions and contra-indications;
- the dosage and method of use of the product; and
- details of the MA and MA holder.

When is it permissible to advertise medicinal products to the general public?

Over-the-counter products may be marketed to the general public, subject to restrictions which include that the advertisement must not:

- give the impression that a medical consultation or operation is unnecessary;
- suggest that the effects of the medicine are guaranteed and not subject to adverse reactions;
- suggest that health could be enhanced by taking the product or could be affected by not taking it;
- refer to recommendations by scientists, professionals or celebrities;
- use exaggerated claims or superlatives;
- use the word “safe” without qualification.

Any advertisement must contain the name of the product and the common name of its active ingredient, any information necessary for the correct use of the product as well as an express invitation to read the instructions for use.

Consumer protection laws also place restrictions on advertising and MA holders must ensure that marketing materials are not misleading nor aggressive. Unsolicited electronic communications must also be avoided.

What restrictions apply to arrangements with healthcare professionals such as gifts, sponsoring and consultancy agreements?

Gifts, pecuniary advantages and benefits in kind may not be given to healthcare professionals subject to the limits and restrictions in the IPHA code. For example, reasonable hospitality expenses may be provided to healthcare professionals to attend certain meetings and events.

Companies are also not precluded from providing reasonable educational support, grants or donating equipment to an institution where this is:

- in response to a written request;
- relevant to the practice of medicine or pharmacy;
- not linked to product promotion;
- paid to the institution rather than an individual; and
- reasonable, modest and in proportion to the scale of the institution.

Free samples may be given to healthcare professionals and only subject to certain restrictions including that:

- samples are provided on an exceptional basis and do not exceed four per year under the IPHA Code;
- any free samples are given in response to a written request;
- such samples are no larger than the smallest presentation of the product on the market and are marked “free medical sample – not for sale” or with words the like effect; and
- the sample is accompanied be a copy of the SmPC.

Healthcare professionals may provide services such as speaking, advisory or research services provided;

- there is a legitimate need for such services and selection of consultants is related directly to this need;
- there is a written contract governing such services;
- no more consultants are retained than necessary;
- records of services are maintained;
- hiring of healthcare professionals is not an inducement to prescribe, purchase, supply or sell a particular product; and
- compensation for such services is reasonable and reflects fair market value.

Companies may organise and sponsor conferences and events with healthcare professionals provided these are held at an appropriate venue that is conducive to the main purpose of the event. In addition, companies may sponsor meetings of healthcare professionals provided expenditure does not extend beyond the general expenses of the meeting. Major meetings or series of meetings should not be sponsored by one company to the exclusion of other available and willing sponsors.

How are parallel imports of medicinal products regulated in Ireland?

Parallel importation is the importation from an EU Member State or a country within the EEA of a medicinal product which is therapeutically equivalent to a product already authorised in Ireland, by an importer who is someone other than the importer appointed by the MA holder of the product on the Irish market. The imported product may be parallel distributed in Ireland provided that the importer obtains an authorisation from the HPRA.

A ‘Parallel Product Authorisation’ is required when the product in question differs to the Irish reference product, but has the same active substances and pharmaceutical form and is therapeutically equivalent to the Irish reference product. If the product does not have or loses its valid MA in Ireland, then any Parallel Product Authorisation will be void.

A ‘Dual Pack Import Registration’ is required where the product in question is the same as the reference product on the Irish market.
What is the current framework for the regulation of medical devices in Ireland?
The HPRA is the competent authority for general medical devices, in-vitro diagnostic medical devices and active implantable medical devices. The role of the HPRA is to ensure that all medical devices on the Irish market meet the requirements of the national legislation which transposes into Irish law three EU Directives which form the core legal framework for medical devices. This includes Directive 90/385/EEC concerning active implantable medical devices, Directive 93/42/EEC concerning medical devices and Directive 98/79/EC concerning in-vitro diagnostics, together known as the Medical Devices Directives ("MDD"). These directives have been supplemented over time by six modifying or implementing Directives.

The National Standards Authority is the notified body in Ireland responsible for performing conformity assessments to ensure compliance with medical device legislation.

Proposals to replace the EU Directives which govern medical devices and in-vitro diagnostic medical devices with a new regulation are currently making their way through the EU legislative process.

What is the structure of the national healthcare system in Ireland?
Healthcare policy and expenditure in Ireland is determined by the Department of Health and implemented by the Health Service Executive ("HSE"). The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, receive state funding but are privately owned. There are also privately owned hospitals in Ireland which receive no state funding. Most medical treatment is available free of charge or subject to a subsidised charge under the public health system.

The Health Information and Quality Authority ("HIQA") is responsible for regulating and investigating public hospitals and institutions as well as researching the cost-effectiveness of health technologies.

What is the current framework for pricing and reimbursement of medical products in Ireland?
Any person who is ordinarily resident in Ireland is legally entitled to either free or subsidised approved prescribed medicines and certain medical and surgical aids and appliances. The prices paid by the HSE for medicines supplied under Ireland’s community drugs schemes are maintained by the HSE on an official Reimbursement List. The prices are set by the HSE by reference to criteria set out in the Health (Pricing and Supply of Medical Goods) Act, 2013 (the “2013 Act”). Any company who wishes to sell a new medicine in Ireland must apply to the HSE to be included on the Reimbursement List.

The 2013 Act also introduced a system of generic substitution and reference pricing in Ireland, which operates as follows:

- The HPRA publishes and maintains a ‘List of Interchangeable Medicines’ which contains products grouped together according to their active substance, strength, pharmaceutical form and the route of administration.
- The HSE sets one price, called the reference price, that it will pay for a group of interchangeable medicines. This is typically the price of the cheapest medicine in the group.
- If a patient wants the more expensive medicine in the group, the patient must pay the difference between the reference price and the retail price.

What is the position in Ireland governing liability for defective or inadequate products?
The Liability for Defective Products Act 1991 (implementing Directive 85/374/EEC) provides for strict liability in relation to defective products. The producer or importer of a defective product, or anyone who holds themselves out as a producer by placing their name or trade mark on a product will be liable for damage or injury caused by the defect.

In addition, the supplier of goods also has obligations under the Sale of Goods Act 1893 and the Sale of Goods and Supply of Services Act 1980, including that the goods be of merchantable quality.

What are the current ‘hot topics’ in life sciences law in Ireland?
In addition to the introduction of new Clinical Trials Regulation in 2016 and the revision of the Medical Devices Directives, “transparency” is the hot topic for life sciences companies. Since January 2015, companies are required by industry codes to document and publicly disclose “transfers of value” made to healthcare professionals and healthcare organisations, either on the company’s website or on a central platform. Transfers of value include direct and indirect transfers of value to healthcare professionals and healthcare organisations whether for promotional purposes or otherwise made in connection with the sale of prescription-only medicinal products. It is anticipated that transparency will continue to be a key focus of future law and policy developments in this sector.
How Can Matheson Help You?
How Can Matheson Help You?

We are the law firm of choice for internationally focused companies and financial institutions doing business in and from Ireland. Commercially focused, innovative, responsive and results driven, we build strong, long term relationships with clients and have the scale and depth of expertise to manage the largest and most complex deals. We pride ourselves on our record of delivering focused, commercial advice and excellent service to our global client base.

We are Ireland’s largest law firm with 74 partners and tax principals, more than 350 legal and tax professionals and a total staff of more than 600. Our headquarters are in Dublin with offices also in London, New York and Palo Alto, California. We were the first European law firm to open an office in Silicon Valley in 1996.

We work extensively with international clients on cross-border commercial and financial services transactions, inward investment issues and other legal requirements. Our offices in London, New York and Palo Alto ensure that there are teams on the ground and in the time zone required.

To discuss investing in Ireland and how best to proceed for the benefit of your business, contact any of the following:

- **Michael Jackson**
  - **Managing Partner**
  - **T**: +353 1 232 2000
  - **E**: michael.jackson@matheson.com

- **Liam Quirke**
  - **London and Dublin**
  - **T**: +44 20 7614 5678
  - **T**: +353 1 232 2000
  - **E**: liam.quirke@matheson.com

- **Robert O’Shea**
  - **Dublin**
  - **T**: +353 1 232 2201
  - **E**: robert.oshea@matheson.com

- **Pat English**
  - **Dublin**
  - **T**: +353 1 232 2330
  - **E**: pat/english@matheson.com

- **John Ryan**
  - **New York**
  - **T**: +1 646 354 6583
  - **E**: john.ryan@matheson.com

- **Mark O’Sullivan**
  - **Palo Alto**
  - **T**: +1 650 617 3351
  - **E**: mark.osullivan@matheson.com

The law stated in this guide is as of August 2015. It is for the general information purposes only.

© Matheson, 2016.