

Morgan Lewis

white paper

bringing a drug to market in the european union

together



regulatory, taxation and corporate issues

why the european union?

introduction



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For businesses in any industry, the European Union (EU) is a market force to be reckoned with. Currently made up of 25 Member States, the EU is the world's largest economy by gross domestic product, and it is the third largest by population.

Its reach and market strength is soon to be increased by the addition of five new Member States: Bulgaria, Croatia, Macedonia, Romania, and Turkey.

Although each Member State of the EU retains some sovereignty over affairs conducted within its own borders, a considerable body of law is now promulgated by the European Commission (EC) and implemented into national legislation in each Member State. This harmonization of laws across the Member States is designed to bolster the principle of free movement of goods, which, in brief, means that once goods have passed the borders of one Member State having met its entry requirements, they are free to be circulated and imported to all other Member States and sold throughout the EU.

However, in light of the health benefits and associated risks that accompany medicinal products, the situation in the EU is much more complicated. Medicinal products are highly regulated in the EU and are subject to a separate, complicated system of approvals that governs how, when, where, and in what form such products will be allowed to be sold in there. Additionally, a number of important, strategic commercial and corporate considerations accompany this complex regulatory environment.

The EU is also home to a multitude of world-class research facilities, and with a large, diverse population and EU-wide clinical trial rules, it represents an excellent choice for the conduct of clinical trials.

The EU, therefore, presents interesting opportunities for life science companies, both before and after the grant of marketing authorizations. Consequently, in order for businesses in the pharmaceutical and devices sector to optimize their presence in the EU market, and to make the most of the extensive resources the EU has to offer, it is important to have an understanding of both the regulatory setting and the associated commercial issues.

Accordingly, this White Paper offers an insight into the regulatory regime in place in the EU for companies wishing to conduct clinical trials or obtain authorizations for medicinal products and medical devices in the EU. This paper also discusses tax, commercial, and corporate considerations that will assist pharmaceutical companies plan appropriate and optimal strategies for entry into or expansion within the EU.

regulatory framework

an introduction to the
regulatory framework



an overview of the regulatory system

The regulation of medicinal products is governed in the EU by Directive 2001/83/EC relating the medicinal products (the “Directive”).

Also known as the Consolidated Directive, it brings many years of separate legislation together into one, detailed document.

It was last updated in 2005, when a number of far-reaching, fundamental, and sometimes controversial changes were made. Although it contains many complexities, the fundamental premise of the Directive is simple: no medicinal product may be placed on the market in the EU unless the relevant competent authority grants a marketing authorization.

It is also worth noting that the legislation has also been adopted by the members of the European Economic Area (EEA): Norway, Iceland, and Liechtenstein. The Swiss system also mirrors EU regulation.

In addition to the requirements that must be met to obtain a marketing authorization, the Directive lays down rules relating to specific categories of medicines (e.g., homeopathic and herbal medicines), manufacture, importation and distribution, labelling and advertising, the classification of medicinal products, and pharmacovigilance.

The Directive, which has been implemented into the national laws of each EU Member State, is accompanied by a number of other EU directives and regulations that address specific areas of medicinal legislation, such as the Clinical Trials Directive discussed in the next section.

pre-authorization considerations

a. establishment

Both general medicines legislation in the EU and the Clinical Trials Directive (see below) require the holder of an authorization for a medicinal product or a clinical trial in the EU to either be established itself in the EU or to have a legal representative who can act on its behalf. In addition, for various activities that are conducted in the EU pertaining to medicines, such as manufacturing, wholesale dealing, and pharmacovigilance, EU medicines law also requires pharmaceutical companies to have a “Qualified Person” at their disposal to oversee certain functions.

Qualified Persons must meet certain specific criteria in order to be classified in this way. It is generally accepted that such Qualified Persons need not be employed directly and may be engaged on a contract or consultancy basis, although depending on the circumstances, direct employment may present the most attractive option. Such considerations will also have an important impact on the choices such as country and corporate vehicle.

Consequently, structuring operations in the EU, including consideration of the preferred corporate structure in the most appropriate EU country is one of the most important decisions a pharmaceutical company can take.

There are a number of choices available for business operations. The principal corporate options are:

- a company (including a subsidiary of an overseas company);
- a branch; or
- a place of business.

For the purposes of this paper it is assumed that business operations will be established in the UK.

Companies (Including Subsidiaries of Overseas Companies)

One option for businesses wishing to establish in the UK is to form a UK company limited by shares. The usual choice for overseas companies is a private company subsidiary of the overseas company. It is possible to establish both private and public companies in the UK—the main difference between the two is that a private company cannot offer its shares to the public. In general, public companies are also more regulated than private companies, and there are additional requirements to be met when setting up a public company.

A company incorporated in the UK has a separate legal identity, distinct from its members (whether a parent company or individuals). As such, its members usually have no legal liability for the company's acts and obligations, except for unpaid share capital and any guarantees given in the case of companies limited by shares.

Branch or Place of Business

A “branch” is part of an overseas limited company organized to conduct business through local representatives in the UK rather than referring it abroad. Companies House gives guidance on what level of activity is required to necessitate registration as a branch. Broadly speaking, if a person is able to deal directly with the UK office instead of the company in its home jurisdiction then the UK office is more than likely to be a branch.

A “place of business” is for companies who cannot register as a branch because their activities in the UK are not sufficient to constitute a branch. Such activities might include internal computer processing, warehousing, or simply a representative office. Essentially a characteristic of a place of business is that its activities tend to be incidental operations.

b. clinical trials

In order to obtain a marketing authorization to place a medicinal product on the market in the EU, it is necessary to have data demonstrating the quality, safety and efficacy of the product in question. The results of clinical trials comprise a large part of this data, and as such, clinical trials represent one of the largest hurdles companies developing potential new drugs face.

The issues that present themselves to pharmaceutical companies attempting to organize a clinical trial can be numerous. For example, depending on the disease in question, obtaining sufficient enrolment number for clinical trials can often be a slow and difficult process, and it can be difficult to obtain the breadth and diversity necessary to ensure results are well balanced. Ethical considerations, such as choice of patient, add additional complications.

As mentioned above, clinical trials in the EU are now governed by harmonized rules that apply to all EU Member States. This enables companies conducting clinical trials to run trials in a variety of countries simultaneously without the need to come to terms with a different set of rules and regulations for each country. It also means that companies have access to a larger number and a greater range of patients (e.g. different skin types, lifestyles, diets etc).

Overview of the Clinical Trials Directive

Clinical Trials are regulated in the EU by European Directive 2001/20/EC (the “CTD”). The CTD has been implemented into national legislation in each EU Member State – in the UK by the Medicines for Human Use (Clinical Trials) Regulations 2004.

The CTD applies to the vast majority of trials conducted in the EU (non interventional trials meeting certain criteria are excluded). Under the Directive, a trial may only be started in a Member State of the EU if it has been authorized by the relevant Competent Authority in that Member State (in the UK, this is the MHRA) and has been given a favorable opinion by an ethics committee. In addition, each trial must have an identified sponsor who is responsible for trial initiation (including obtaining authorization), management, conduct, and pharmacovigilance.

To provide public health protection, the CTD sets out the requirements for obtaining informed consent from participants and, in particular, sets out the process that must be followed in relation to specific vulnerable groups. In addition, both the European Medicines Agency (EMA) and the national regulatory authorities will conduct mandatory good clinical practice inspections, and the findings from these inspections, together with details of each authorized trial, will be available for all other Member States' regulatory authorities to see on a new European database for clinical studies.

Failure to comply with certain aspects of the CTD may constitute a criminal offense and carry a prison sentence of up to two years, in addition to a fine.

The CTD is complemented by Directive 2005/28/EC on good clinical practice (“GCP”). The GCP Directive sets forth the detailed rules and procedures that aim to assist and guide companies involved in clinical trials.

obtaining a marketing authorization

a. general requirements

In order to obtain a marketing authorization, applicants must submit a full dossier to the relevant competent authority that details, among other things, the common or scientific name, invented name, qualitative and quantitative particulars of the product, the proposed therapeutic indications, contra-indications and adverse reactions, as well as the results of pharmaceutical and pre-clinical tests and clinical trials. Marketing authorizations are valid for an initial period of five years, after which they may be renewed for a further five-year period provided they satisfy a re-evaluation of the risk-benefit balance.

Last year's changes to the medicines legislation also introduced a new provision dubbed the "sunset clause," which provides that a marketing authorization will no longer be valid if a product has not actually been placed on the market in the first three years following grant of its authorization, or is no longer on the market for a consecutive period of three years.

Once a marketing authorization has been granted, the holder is under a continuous obligation to update the authorization in order to ensure that scientific progress and new regulatory requirements are respected, and in particular, any information which may influence the evaluation of the benefits and risks of the product. Accordingly, marketing authorization holders have a continuing duty to have in place stringent pharmacovigilance procedures and to keep abreast of developments and advances within the medicines arena.

b. which authorization?

One of the most important considerations a pharmaceutical company has to make when bringing a drug to market in the EU is which marketing authorization to apply for. Previously, there were only two possible routes to authorization, but changes to the legislation in 2005 mean that applicants can now have three possible choices.

Prior to the introduction of a uniform, EU-wide system, each Member State had responsibility for granting and regulating medicinal products within its borders. Updates and amendments to EU legislation governing medicinal products over the years have resulted in the harmonization of the approvals system to help facilitate the free circulation of authorized medicinal products throughout the EU. However, as is illustrated by the following, in many ways the approvals system remains somewhat disjointed.

Depending on a product's eligibility, each of the authorization routes offers various advantages and disadvantages, as further detailed below.

The Centralized Procedure

The centralized procedure is compulsory for products developed by means of certain biotechnological processes, orphan drugs and new active substances for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, and from 1 May 2008, auto-immune diseases and other immune disfunctions and viral diseases. In addition, it is open to medicinal products containing a new active substance never before authorized in the EU, medicinal products that can be proven to have a significant therapeutic, scientific or technical innovation, or where the authorization would be in the interests of human or animal health.

Products authorized pursuant to the centralized procedure are granted marketing authorizations that cover all EU Member States and the EEA. A further distinguishing feature of this route includes the requirement for the marketing holder to also secure a single EU-wide trademark for the product. However, the convenience of the centralized procedure is also accompanied by fees that are significantly higher than the national procedure.

National Marketing Authorizations

With the exception of products granted a marketing authorization under the centralized procedure as set out above, all products are granted marketing authorizations on a country-by-country basis by the competent authorities in each Member State. Such marketing authorizations permit the holder to market the product in question in the Member State concerned, subject to any restrictions or requirements that accompany the authorization.

The Mutual Recognition Procedure and Decentralized Procedure

Medicines legislation also foresees the possibility that most pharmaceutical companies will wish to market their products in more than one EU country, and provides two mechanisms to applicants that avoids the need to submit full marketing authorization applications in each country.

The first of these, the mutual recognition procedure, enables pharmaceutical companies who already hold a marketing authorization in one EU Member State to ask additional Member States to recognize the marketing authorization that has already been granted. The procedure involves the preparation of an assessment report by the original Member State that is forwarded to the additional Member States for their consideration. Assuming the other Member States agree with the report, a marketing authorization will then be issued for the product in the Member States concerned. However, the Mutual Recognition procedure often sees disagreements between Member States that can hold up the procedure and lead to delays. For such occasions, there is a detailed disputes procedure that must be followed.

The decentralized procedure, which was introduced during the changes to the legislation in 2005, aims to avoid some of the potential disputes between Member States and the resulting delays to authorization by engaging each of the Member States the applicant wishes to apply to at the time the first marketing authorization is made. Consequently, this procedure is only open to products that have not yet been granted a marketing authorization in the EU. Under the decentralized procedure, the applicant chooses one Member State to be its reference Member State. The chosen reference Member State then prepares a draft assessment report which is submitted to the other Member States for their consideration and approval. For disputes, the decentralized procedure follows a course of action that is similar to that of the Mutual Recognition disputes procedures.

c. data and market exclusivity

Once a product has been granted a marketing authorization in the EU, the holder's thoughts will unsurprisingly turn to maximizing market share for the product and ensuring it is adequately protected. EU medicines legislation has created a protection mechanism for original products that is entirely separate from patent protection and allows innovative products a set period during which they enjoy exclusivity on the market.

Data exclusivity refers to the period in which generic product applicants cannot rely on the dossier of the original product (the "reference product") for the purposes of obtaining a marketing authorization. Prior to changes to the legislation that came into force on October 30, 2005, this protection period was set at either six or ten years, depending on the country in question.

However, one of the changes made in 2005 was to introduce a new, uniform 8 + 2 + 1 protection period throughout the EU. It is important to note that this new protection period only applies to products granted after the changes came into force. Under the new system, the data protection period is now set at eight years, meaning that the marketing authorization holders of reference products enjoy a protected period of eight years before applicants may submit applications for generic products that rely on the original data in the reference product's dossier.

Following this initial eight years, even though generic applicants can begin preparing generic versions of an existing product by submitting their abbreviated applications, they must wait a further two years before being able to actually start selling generic versions of a reference product.

This ten year data and market protection period can be further extended by one year, if, during the first eight years, the reference product authorization holder seeks and obtains authorization for one or more new therapeutic indications that represent a significant clinical benefit when compared with existing therapies.

Consequently, authorization holders of reference products enjoy, under the recently updated system, a protection period of at least ten years.

d. patent protection

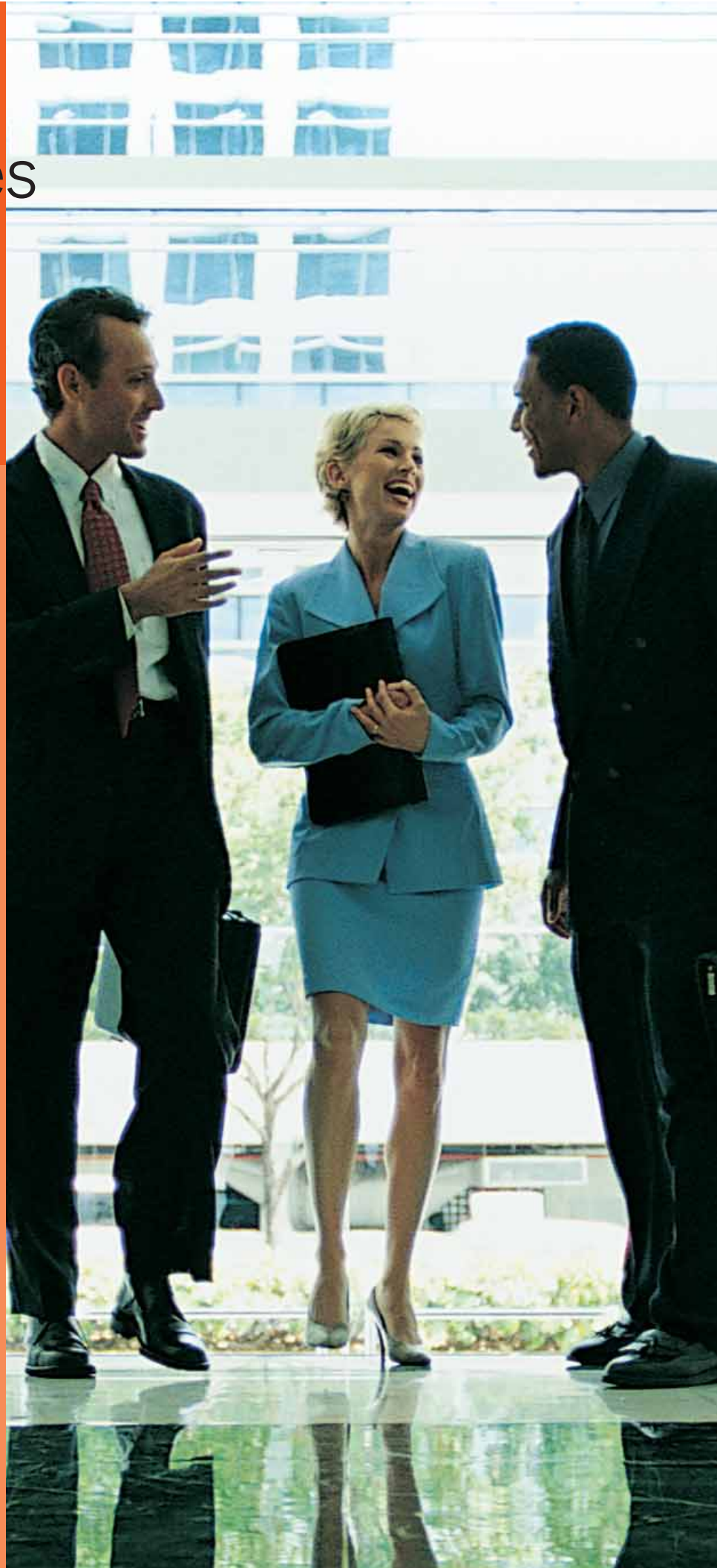
It is important to note that data and market exclusivity are entirely separate from patent protection, though in order to accommodate the two-year market protection period, patent legislation has been amended to make it clear that submitting a generic application and conducting the necessary preparatory work to do so will not be deemed patent infringement.

As further incentive to innovator pharmaceutical manufacturers, the EU also allows such companies to apply for supplementary protection certificates (“SPCs”) in respect of new products.

SPCs can only be applied for once a patent and marketing authorization have been granted in respect of a particular product, and they cover the time lapse between the date of patent application and the grant of a marketing authorization up to a maximum of five years (resulting in a monopoly of up to 15 years on marketed drugs). They cover a combination of what was claimed in the patent in relation to the marketed drug and what is covered by the marketing authorization.

taxation issues

taxation structure in
the European Union



different structures
for the establishment
of an EU presence

In determining the optimal business structure, it is important to consider the taxation consequences which may arise. As discussed above, an EU “establishment” may be required or otherwise a “legal representative” in the EU.

From a structural perspective the choice is between the establishment of a subsidiary or a branch, or alternatively, the non-EU entity could enter into a contractual relationship with an EU entity or individual.

Each of these alternatives will have different tax consequences, as will the precise arrangements between the EU entity/presence and the non-EU company.

Set out below is a discussion of the most important tax issues which should be considered when establishing a presence in the EU.

General

Both the CTD and the general medicines legislation in the EU require that the holder of an authorization for a medicinal product or a clinical trial in the EU should either be established in the EU or have a legal representative in the EU that can act on behalf of the non-EU entity (“Parent Co.”). This requirement may be satisfied by Parent Co. entering into a contractual relationship with an unrelated third party to act as the legal representative, or alternatively establishing its own branch or subsidiary.

As an initial comment, it is generally preferable from a taxation perspective to establish a structure which avoids the imposition of tax in jurisdictions other than the home jurisdiction of Parent Co. The advantage of only paying tax in Parent Co’s home jurisdiction is that there should be no risk of double taxation, which may arise, for example, if tax paid in a jurisdiction outside the home jurisdiction is not fully creditable in the home jurisdiction (because, for example, Parent Co has tax losses, so it pays no home jurisdiction tax, or because the tax rate in the foreign jurisdiction is higher than the rate in the home jurisdiction, so an excess foreign tax credit results).

Assuming that Parent Co. is situated in a country that has a double tax treaty with the relevant EU jurisdiction, Parent Co. should only be subject to tax in that EU jurisdiction to the extent that it carries on business in the EU jurisdiction through a “permanent establishment”. Most double tax treaties are based on the OECD Model Convention, including the US/UK double tax treaty (the “Treaty”), so broadly the analysis should be similar for each jurisdiction.

For the purposes of the discussion in this tax section, it is assumed that Parent Co. is a US corporation which is entitled to benefit under the Treaty, and that the EU jurisdiction for the establishment is the UK.

A permanent establishment is defined in the Treaty as a fixed place of business, and includes a branch, an office or a place of management, but does not include an agency, unless the agent has, and habitually exercises, a general authority to negotiate and conclude contracts on behalf of the principal. Notwithstanding this general rule, an agency will not give rise to a permanent establishment if the principal operates through a broker or an independent agent, where that person is acting in the ordinary course of his business.

Contractual Relationship

If Parent Co. was simply to enter into a contractual arrangement with an unrelated third party to act as its representative in the UK, then provided that the representative had no power to enter into binding contracts on behalf of Parent Co., no permanent establishment should exist and Parent Co. should not be subject to corporate tax in the UK. Parent Co. would be required to purchase services from third party providers – for example the clinical trials could be carried out by a contract research organization (“CRO”) and marketing and product support could also be purchased. Parent Co. would directly sell any products developed to customers.

While a contractual relationship may produce a desired tax result, there may be a number of commercial reasons why such an arrangement may be unattractive. In particular, it may be difficult to find someone willing to act as a representative for clinical trials, given the liabilities which may arise. In addition, Parent Co. may be concerned about leaking information into the market place, especially if no patent is obtained – as a consequence, Parent Co. may prefer its own employees to perform the work, rather than a third party, as this may permit it to obtain stricter employee non-compete and confidentiality agreements. Further, Parent Co. may wish to establish a UK presence under its own name to provide greater credibility in the UK, to demonstrate a commitment to the UK market, to provide greater name recognition etc.

Establishment of a Branch

If Parent Co. did require an actual presence in the UK, then the choice would be between the establishment of a branch or a subsidiary. It is assumed that, given the role to be played by the UK entity, a place of business would not be appropriate.

The simplest and cheapest form of presence would be for Parent Co. to establish a branch in the UK. The first issue is to determine whether the activities of the branch created a permanent establishment of Parent Co. in the UK. No permanent establishment will be created if the activities of the branch are limited to collecting information. In addition, no permanent establishment would be created if the activities in the UK could be characterized as “preliminary or auxiliary” to carrying on business. Under the old Treaty (which was superceded a few years ago) this exemption specifically included scientific research activities. The view of the UK tax authorities was that research activities where no product had yet been developed would fall within this exemption, but that once a product had been developed any future research was enhancement of an existing product, and was therefore not “preparatory” in nature, as there was a product that could be exploited. The scientific research exemption was deleted in the current Treaty, and thus it may be difficult to argue that it applies. In any event, by the time Parent Co. conducts clinical trials in the UK, it is likely that the product would have been developed to a stage where the “preparatory and auxiliary” exemption is unlikely to be available in any event.

Assuming that a permanent establishment is created, what are the consequences for Parent Co.? The main consequence is that Parent Co. would be subject to UK tax on the profits attributable to the activities of the permanent establishment. Initially, while clinical trials are being conducted, it is likely that there will be losses generated, and thus UK tax should not be an issue. In addition, Parent Co. should be able to use the losses to reduce its taxable income in its home jurisdiction (assuming of course that there are sufficient taxable profits available), although as will be discussed below a US Parent Co. should be able to achieve the same result by establishing a UK subsidiary and filing a “check the box” election, electing to disregard the UK subsidiary for US tax purposes.

However, when a marketing authorization is obtained, and products are sold in the EU, the UK permanent establishment is likely to become profitable. The principal issue at this time will be to calculate the profits that are subject to UK tax – namely, the profits generated by the activities of the UK permanent establishment. In theory, the profits of the permanent establishment are calculated as if the UK branch was a separate and distinct enterprise – this sounds like a simple concept, but the level of profit is often difficult to determine, particularly given the fact that there are no formal arrangements in place between the UK branch and Parent Co. (such arrangements are not possible as Parent Co. and the UK branch are legally the same entity, and an entity cannot contract with itself). This may lead to long and expensive negotiations with the UK tax authorities before an acceptable level of profit is agreed.

The advantages of establishing a branch include the fact that it is fairly simple and inexpensive to establish, with low ongoing costs. It may be possible to operate free from UK tax for a period of time, and initial losses should be capable of being utilized by Parent Co. to reduce its taxable income in its home jurisdiction. Disadvantages would include exposure of Parent Co. to unlimited liability in the event of a claim against the branch (although Parent Co. could establish a special purpose subsidiary to shield it from such claims), potentially long and expensive negotiations with the local tax authorities to determine the level of profit which is subject to local tax (which may not necessarily result in a favorable determination) and the need to disclose the accounts of Parent Co. in the UK.

Establishment of a Subsidiary

As an alternative to the establishment of a branch, Parent Co. may decide to establish a UK subsidiary ("Sub Co."). As a UK resident company, Sub Co. would be subject to UK tax on its worldwide income and capital gains. The standard UK corporate tax rate is 30%, while small companies which have income below £300,000 are subject to tax at only 19%. A tapered rate applies to companies with income between £300,000 and £1,500,000. Sub Co. may pay dividends free from withholding tax to Parent Co., and providing that certain criteria are satisfied Sub Co. may also pay interest on borrowings from Parent Co. without any withholding tax charge.

The establishment of a subsidiary has a number of benefits. It is a separate legal entity, and any claims including product and employee liability claims may only be made against it, not Parent Co. In addition, there is greater certainty as to the level of profit which is subject to UK taxation, especially through the use of an inter-company services agreement (see below). From a practical perspective, it will be easier to acquire premises in the UK through a local company and there is no requirement to disclose the accounts of Parent Co. A further benefit arises if the exit strategy involves the sale of the UK business – shares in Sub Co. may be sold free from UK tax, whereas the sale of branch assets in the UK will be subject to UK tax on disposal. The disadvantages of a subsidiary include increased establishment and ongoing costs, and initial losses cannot be used to reduce the taxable profits of Parent Co. (absent a check the box election – see below).

The amount of tax payable by Sub Co. will depend upon the role it plays. Will Sub Co. merely provide services to Parent Co., or will it act as a principal in the development and ongoing conduct of business in the EU?

The taxation analysis can vary quite significantly depending on the role to be played by Sub Co. Sub Co. could simply provide services to Parent Co. in return for an arms'-length fee. In this capacity, it would be providing services in the same way as a third party may be contracted by Parent Co. to provide services – for example, a CRO which conducts clinical trials for Parent Co in return for a fee.

Any rights which are developed from the activities carried on by Sub Co. would belong to Parent Co., which would itself exploit the rights, enter into contracts with customers and receive the revenue from the sales. In these circumstances Sub Co. is unlikely to receive substantial income. Going forward, Sub Co. could be engaged by Parent Co. to provide support services and/or marketing services, for which it would receive an arm's-length fee. Again, it is unlikely that Sub Co. would earn substantial profits.

Alternatively, Sub Co. could act as the principal in its own right. This would involve Sub Co. taking an entrepreneurial risk, in exchange for a share of the future rewards. Thus Sub Co. would pay for the clinical trials, potentially additional research and development activities and future marketing activities. If a product were to be developed which was marketed and generated revenue, then Sub Co. would expect (and the UK tax authorities would require) that it would receive a share of the revenue earned from the exploitation of that product. The main issue would be to determine the reward (namely which rights) that Sub Co. should receive in exchange for taking the entrepreneurial risk on the clinical trials, research and development and marketing activities. Clearly, if valuable rights are developed the consequences of the ownership of some or all of these rights being given to Sub Co. would need to be carefully considered, especially as it should result in Sub Co. earning substantially more income than if it acts a service provider.

It would be fairly typical for Sub Co to incur expenditure on research and development or clinical trials, in return for specified distribution rights— for example, Sub Co. could receive the UK distribution rights to any product which is developed from the activities carried on by Sub Co. Alternatively, consideration could be given to rewarding Sub Co. with a percentage of the net cash proceeds from sales in the UK of the product which is developed, which may be appropriate if Sub Co. is engaged in marketing activities on behalf of Parent Co. If both Parent Co. and Sub Co. engage in the relevant activities, then the revenue generated could be divided between them, with Parent Co. and Sub Co. each receiving a portion the net cash proceeds from sales of the product in the UK, based on their respective contributions.

Clearly, the appropriate reward for the entrepreneurial risk which is taken will depend heavily on the precise factual circumstances, and will need to be considered on a case by case basis.

It should be noted that any expenditure incurred by Sub Co. on research and development, clinical trials or marketing and any other activities should give rise to UK tax losses, which should be available to reduce future taxable income earned by Sub Co.

By providing Sub Co. with a share of future benefits, one of the major disadvantages of the traditional structure where a UK entity is paid a fee for providing services, such as clinical trials may be overcome.

The problem arises because the tax authorities would expect a third party which is providing services to an unrelated party to earn a profit from the provision of those services – thus Sub Co. should earn a profit from providing services to Parent Co. This profit would be subject to tax in the UK. However, if Parent Co. has no product to sell it will not be earning any income. As consequence, you may have the somewhat anomalous situation of the group (as a whole) paying tax at a time when it is earning no income, has no product to sell nor may it ever develop and sell any product from which it can earn income.

In these circumstances, the inter-company pricing rules may be satisfied by an arrangement whereby Parent Co. funds the expenditure of Sub Co., and Sub Co. receives some distribution rights (or a percentage of the revenue generated) to any product which is developed from the activities of Sub Co. Based on our prior experience in negotiating such arrangements with the UK tax authorities, this should provide Sub Co. with an arms-length reward for the entrepreneurial risk which it has taken, and should therefore satisfy the inter-company payment rules.

Another point to note is the ownership of any rights which are developed. Generally, by the time clinical trials are undertaken, the initial research has been completed and Parent Co. should have a patent on the product Accordingly, it is unlikely that any intellectual property will be developed that will be owned by Sub Co., but any inter-company documentation should make this point clear. If intellectual property is to be licensed to an EU entity, then the royalty paid by the EU entity must be an arm's-length royalty. In addition, consideration will need to be given to any local withholding tax on royalty payments.

Inter-Company Arrangements

Regardless of the precise role to be played by Sub Co., the relationship and transactions between Parent Co. and Sub Co. will need to be carefully considered. Firstly, it will be necessary to ensure that the activities of Sub Co do not create a permanent establishment of Parent Co. in the UK (thus potentially exposing Parent Co. to UK tax). Secondly, the UK tax authorities (and the IRS) will require that any dealings between Parent Co. and Sub Co. be conducted on an arm's-length basis, with a full arm's-length price paid for any goods or services which are supplied between the two companies.

It should be possible to manage these two issues through the use of an inter-company services agreement. An inter-company services agreement can be used to limit the power of Sub Co., particularly to ensure that Sub Co. cannot enter into binding contracts on behalf of Parent Co. thereby reducing the risk that Sub Co. may be treated as a permanent establishment of Parent Co.

In addition, the inter-company services agreement will also state the consideration to be paid for the inter-company services and goods. This agreement will provide written evidence to support the inter-company pricing methodology that has been chosen, and as evidence in existence from the time the inter-company services were first provided, will constitute quite persuasive evidence. Provided that the pricing methodology chosen is reasonable and supportable, it is unlikely that the UK tax authorities will challenge the inter-company pricing methodology.

The acceptable inter-company pricing methodology will depend upon the precise services to be provided. If the services are similar to those provided by a CRO or are support services which could easily be purchased from a third party provider, then it is likely that a cost plus fee should be acceptable. By contrast, marketing services would usually require a fee calculated by reference to a percentage of sales.

Check the Box Election

As was discussed above, losses generated by the activities of a branch are generally available to reduce the taxable income of Parent Co., whereas losses generated by a UK subsidiary are not. This general rule may be modified where Parent Co. is a US corporation which files a “check the box” election in respect of Sub Co. The effect of a check the box election is that Sub Co. is disregarded for US tax purposes. Parent Co. is therefore treated as carrying on business in the UK through a branch, and any losses generated by Sub Co. should be available to reduce the taxable income of Parent Co. for US tax purposes. The check the box election has no effect for UK tax purposes, and thus Sub Co. will continue to pay UK tax on its worldwide income and capital gains. The UK corporate tax paid by Sub Co. should be available as a credit against the US tax payable by Parent Co.

While the filing of a check the box election may provide a benefit while the UK operations are loss-making, a disadvantage may arise once the UK operations become profitable, as any opportunity to defer recognition of Sub Co.'s income for US tax purposes will no longer be available (as a corporation, subject to the application of the controlled foreign corporation rules, the income of Sub Co. should only be subject to US tax as and when a dividend is paid by Sub Co. to Parent Co.). The advantages of deferring the recognition of income for US tax purposes is twofold. Firstly, Parent Co. could take advantage of the differential in tax rates. This saving in tax could be quite significant, and the funds saved can be used to provide funding for the non US operations, such as funding growth in the EU. In addition, if Sub Co. is a corporation for US tax purposes, there will be greater flexibility over the timing and use of tax credits in the US for corporation tax paid by Sub Co.

raising future funds

how the AIM market
can help a company
fund its future growth
and raise its profile
in Europe



why AIM?

One of the challenges that any company faces is raising money to fund future growth. This pressure is vastly increased for life sciences companies who are required to fund costly clinical trials.

AIM is the London Stock Exchange's market for smaller companies. While AIM membership is available to companies from all sectors and from all over the world, AIM, with its flexible approach to regulation and streamlined admission process, has proved exceptionally attractive to Life Sciences companies looking to raise capital and enhance their profile within Europe.

A company joining AIM gains all the benefits of flotation on a public market in addition to the advantages of being quoted in London for example:

- exposure to the deepest pool of global capital in the world, both at the time of flotation and later through further issues;
- the creation of a market in the company's shares, broadening its shareholder base and potentially providing an exit for existing shareholders;
- the flexibility to raise its profile with a view to expanding its operations into new overseas markets;
- access to international investor expertise through a unique globally respected market;
- a flexible yet internationally respected regulatory regime;
- currency for and easier rules on acquisitions; and
- eligibility for a range of tax benefits.

At the end of August 2006, there were 1,574 companies trading on AIM with a total market capitalization in excess of £50 billion of which 33 are US companies and 43 are Life Sciences companies.

admission requirements

Whatever the company's country of origin, the AIM application process remains the same with the key requirement being that the company must be appropriate for the market, a decision made by the company's Nominated Advisor (or "NOMAD"). There are no restrictions on the size of the company or its specific activities.

Furthermore, there are no restrictions on the number of shareholders, no minimum number of shares required to be in public hands, and no required trading track record.

The Admission Process

NOMAD

Each company must appoint and retain a NOMAD at all times. The NOMAD will be one of a number of firms of experienced corporate financiers who are approved by the London Stock Exchange. There are a number of NOMADs whose experience is specifically in field of Life Sciences and whose help and support would be invaluable to any Life Sciences company seeking admission to AIM.

The NOMAD is appointed by the company but is responsible to the London Stock Exchange for the confirmation that the company is suitable for admission to AIM and for ensuring the company's compliance with the AIM rules post-admission. The NOMAD will take responsibility for coordinating the admission process with the assistance of the company, its lawyers, accountants and other advisors.

Broker

Each company must appoint and retain a broker at all times. The broker will be a securities house which is a member of the London Stock Exchange. The broker may be the same firm as the NOMAD or an independent broker may be chosen. The broker takes responsibility for dealings in the company's shares.

Admission Document

A company joining AIM must publish an Admission Document containing the information required by the AIM Rules of the London Stock Exchange.

While it is possible to have shares admitted to AIM without raising money, most companies will take the opportunity to raise money by way of a placing of new shares. Following the implementation of the EU Prospectus Directive, a company may not make an offer to the public in the United Kingdom without producing a prospectus which is first approved by the United Kingdom Listing Authority, unless such an offer is an "exempt" offer. To be exempt the offer must satisfy certain prescribed criteria which include not making the offer to more than 100 persons, other than "qualified investors" as the term is defined in the relevant legislation. The NOMAD will seek, if at all possible, to ensure that such criteria are met. Accordingly, it is likely that the applicant company will be required to produce only an Admission Document, compliant with the AIM Rules. This document may look like a prospectus, but it will contain much less information and, most importantly will not need to be approved by the United Kingdom Listing Authority.

An Admission Document provides details about the company and its securities which are to be admitted to AIM, so that investors can assess the value of the securities and make an informed judgment as to their future performance in the market.

In addition to information on, inter alia, the history and background of the company, its products, business and directors, there are certain specific requirements which the Admission Documents must contain:

- annual audited accounts for the last three years (or less if the company has been trading for less than three years);
- financial information on any business or company which the company intends to acquire;
- a statement that the company has sufficient working capital for its present requirements (at least 12 months from the date of the Admission Document);
- the name of any person who has received, within the previous 12 months, any fees, securities or other benefits with a value of £10,000 or more;
- details of any lock-ins (see above);
- details of any significant shareholders (3% or more);
- in relation to each director there are detailed information requirements covering, inter alia, each directors interests in shares, employment terms, other directorships, insolvencies in which the director has been involved; and
- a responsibility statement confirming that each of the directors accepts responsibility, individually and collectively, for the information contained in the document, and that “to the best of the knowledge and belief of the directors (who have taken all reasonable care to ensure that such is the case), the information contained in the admission document is in accordance with the facts and does not omit anything likely to affect the import of such information”.

General Duty of Disclosure

The applicant company must include in the Admission Document “any other information which it reasonably considers necessary to enable investors to form a full understanding of:

- (i) the assets and liabilities, financial position, profits and losses, and prospects of the applicant and its securities for which admission is being sought;
- (ii) the rights attaching to those securities; and
- (iii) any other matter contained in the admission document.”

Who has Responsibility for an Admission Document

The persons responsible for an Admission Document include (a) the company, (b) each director of the company at the time it is published (this includes shadow directors, i.e. people in accordance with whose instructions the directors of the company are accustomed to act, regardless of their official position), and (c) every person is named in the Admission Document as a proposed director.

The Admission Document must contain the responsibility statement set out under “Specific requirements” above.

Placing/Introduction Agreement

The company and its directors will enter into a Placing or Introduction Agreement with the NOMAD and the broker, under which the NOMAD and the broker agree to perform their respective functions (including placing the company's shares if relevant), and the company and its directors undertake to fulfill their role in the placing and give warranties and (in the case of the company) indemnities in relation to the company.

“Fast track” designated markets route

The London Stock Exchange has introduced a “fast track” procedure for companies already listed on one of the “Designated Markets.” Both the NYSE and NASDAQ are designated markets for these purposes. The procedure is designed to simplify the AIM admission process for companies that have been traded on certain major markets (known as AIM Designated Markets) for at least 18 months. These companies can use their existing annual report and accounts as a basis for a complementary quotation on AIM.

Tax Benefits for Investors in AIM Companies

In certain circumstances a quotation on AIM can provide the opportunity for UK tax paying investors in non-UK companies to take advantage of UK tax benefits. These reliefs mostly apply to unquoted companies and for this purpose, qualifying companies traded on AIM are regarded under UK tax legislation as unquoted. The reliefs may not apply where the company is listed on another Recognized Stock Exchange. These benefits include capital gains tax benefits, inheritance tax benefits, and continued relief under the Enterprise Investment Scheme and Venture Capital Trust rules.

Time and Cost

The Admission process for AIM (other than for companies on the fast track designated markets route) usually takes approximately three to four months. The length of time is largely dependent on the complexity and type of the company involved, how well organized the company is and therefore how quickly information is supplied and how accurate information that is provided is, which will have an impact on the amount of time spent by the lawyers and other advisors carrying out due diligence and verification process.

Costs will comprise fees for the various members of the admission team and will generally amount to between eight to ten percent of the amount raised.

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