The Treatment
A guide for life sciences companies coming to Europe

TaylorWessing
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1. Introduction

Investing in the European life sciences sector, in particular pharmaceuticals, biotechnology and medical devices, can unlock a substantial portion of the global life sciences market. IQVIA Institute reports that medicine spending in the top five European Countries was US$177.5 billion (15%) of the global amount in 2018.

The European medicines market as a whole is second only to North America and boasts growth in 2018 of 3.9%, representing considerable opportunities for investment.

The Treatment is designed to provide a high level overview of some of the most important issues to consider for any life sciences company seeking these opportunities by coming to Europe.
Regulating Europe

Life sciences product regulation in Europe is largely based on European Union (EU) rules. The EU is an economic and political partnership between 28 European countries (27 after the UK leaves), founded on treaties agreed by all member states. These agreements set out the EU’s fundamental tenets, including the single market. This is a borderless internal market enabling most goods, services, money and people to move freely. The single market requires the EU to enact rules applicable to all member states, aimed at uniformity in how most products are regulated. The EU, together with the non-EU countries Iceland, Liechtenstein and Norway, forms the European Economic Area (EEA). These countries also share in the single market and they are closely integrated by the EU rules applicable to life sciences products. After it formally leaves the EU, and much like Switzerland which is also a non-EU/EEA country, the UK will make its own laws, but these are expected to remain closely aligned to the EU in the areas discussed in this guide (see Chapter 13, Brexit).

The EU/EEA rules relevant to life sciences products are found in a number of Regulations and Directives. All Directives have to be implemented by each EU/EEA member state into its national law. The result is that their implementation varies between member states, so that a ‘one size fits all’ approach to compliance in Europe is not always possible. Regulations, by contrast, are directly applicable in all EU/EEA countries.

The European Medicines Authority (EMA) is the authority responsible for protecting and promoting human and animal health within the EU/EEA. It does so by evaluating, authorising and monitoring medicines. Due to Brexit, the EMA moved from London to Amsterdam in 2018.
2. Medicinal products and medical devices – an overview of their regulation in Europe
Marketing authorisations

Under European legislation, a medicinal product is defined as any substance or combination of substances presented for treating or preventing disease in human beings. This includes combinations of substances that may be administered to human beings to make a medical diagnosis or to restore, correct or modify their physiological functions.

Before a new medicinal product can be placed on the market in Europe it must receive a marketing authorisation. There are four ways in which a marketing authorisation can be obtained in the EU/EEA.

► the centralised procedure, directly through the EMA – this allows applicants to obtain an EU/EEA-wide marketing authorisation. This is mandatory for certain medicines, such as biological and biotechnology products manufactured by recombinant DNA technology

► the mutual recognition procedure – this is available for medicines that have already received a marketing authorisation in one EU/EEA member state. It is based on the principle that one member state should recognise a marketing authorisation correctly granted by another member state and, on the basis of that, grant a marketing authorisation in respect of its own country
- **the decentralised procedure** – this is similar to the mutual recognition procedure, but applicable for medicines which have not received a marketing authorisation at the time of application

- **a national procedure** – this is for medicines that fall outside the mandatory scope of the centralised procedure and are intended for marketing only in one or a few countries.

To apply for a marketing authorisation, an applicant must be ‘established’ in the EU/EEA. Non-EU/EEA companies will typically achieve this by setting up a subsidiary in a chosen EU/EEA country.

Companies may consider seeking **formal scientific advice** from the EMA as to the tests and trials that should be performed in order to demonstrate their product’s safety, efficacy and quality.

For new active substances a ‘full application’ must be made, which is accompanied by a dossier of information relating to the medicine, including pharmaceutical tests, preclinical tests and clinical trials. For medicines containing existing active substances, ‘abridged applications’ are possible. These avoid the need to repeat the pre-clinical and clinical trials data of the original, by making reference to this data in the abridged application (see also **data exclusivity** below).
Manufacturers, suppliers and brokers

Medicines regulation now extends to the entire supply chain for medicinal products, requiring the manufacture, supply and brokering of medicines in Europe to have the relevant licence:

- Making, packaging (or ‘assembling’) and importing human medicines in or to Europe all require a site-specific manufacturer’s licence.

- Wholesaler dealer licences are required for the sale or supply of medicine to anyone other than the patient using the medicine. Pharmacists are now also required to have a wholesaler licence if they supply medicines to anyone other than directly to the public.

- A broker acts as an intermediary for another party in the supply chain, and does not pay for, own or physically handle the product. Wholesale dealing and brokering are different activities, and so companies which perform both activities are required to hold a wholesaler’s licence and a broker’s licence where required by the respective national law. In a few countries brokerage only needs to be notified to the competent authorities.

The formalities for obtaining these licences vary between European countries. Obtaining a relevant licence in one member state can, in some circumstances, permit certain activities in other member states without the need for the same type of licence in the other member state.
Pharmacovigilence

Marketing authorisation holders in Europe are required to comply with ongoing pharmacovigilance obligations once their product is on the market. The obligations on marketing authorisation holders include:

► the submission of a risk management plan
► keeping a pharmacovigilance system and to audit this system at intervals, and
► the reporting of suspected adverse reactions.

Where uncertainty about some aspect of the efficacy of a product has been identified the marketing authorisation holder can be required to perform post authorisation efficacy studies.

Marketing authorisation holders must also nominate an appropriately qualified person responsible for pharmacovigilance in the EU/EEA.
Qualified persons

Marketing authorisation holders in Europe are required to nominate at least one qualified person (QP) in relation to their marketing authorisation. The QP must be permanently and continuously at the marketing authorisation holder’s disposal, and is responsible for ensuring that batches of the medicinal product have been manufactured in accordance with all relevant requirements and legislation.

Where the marketing authorisation holder imports the medicinal product from outside the EU/EEA, the QP must ensure testing within the EU/EEA to the requirements of the marketing authorisation and any other tests or checks necessary to ensure quality. The QP must also be satisfied that the medicinal products have been manufactured in accordance with good manufacturing practice (GMP) standards which are equivalent to those of the EU/EEA.

QPs must have a minimum level of scientific qualifications and industry experience. In some countries, such as the UK, smaller companies are permitted to employ a ‘contracted QP’, who provides a part time service under contract rather than being an employee of the company.
Data exclusivity

A company that has obtained a marketing authorisation on a product for the first time enjoys a period of ‘data exclusivity’. During this period, the authorisation holder’s pre-clinical and clinical trials data may not be referred to in an abridged application for the same drug substance by another company (this does not, however, prevent another company performing its own trials and submitting a full application).

Data exclusivity applies according to the 8+2+1 regime. That is, eight years from grant of the marketing authorisation a third party can use the pre-clinical and clinical trial data of the original marketing authorisation in their regulatory applications, but cannot market their product until after 10 years from the grant of the marketing authorisation.

An additional one year of market exclusivity may be obtained by the authorisation holder if they are granted a marketing authorisation for a significant new indication of the medicinal product concerned.
**Orphan drugs**

To encourage companies to develop drugs for treating rare diseases, European legislation provides certain incentives. These include a 10 year period of exclusivity following the grant of a marketing authorisation. This is an absolute exclusivity, during which no directly competing or similar product can be placed on the market. For a product to be classed as an orphan medicine, it must be intended for the diagnosis, prevention or treatment of either:

- a life-threatening or chronically debilitating condition affecting no more than five in 10,000 people at the time of submission of the application for orphan designation, or
- a life-threatening, seriously debilitating or serious and chronic condition for which, without incentives, it would be unlikely that the revenue after marketing of the medicinal product would cover the investment in development.

There must also be no other satisfactory method available for the diagnosis, prevention or treatment of the condition or, if there is such a method, the new medicine must be of significant benefit to those affected by the condition.

An application for orphan drug status is separate to an application for a marketing authorisation and orphan exclusivity should not to be confused with data exclusivity.
Medical devices

European legislation governs the requirements that manufacturers must meet before marketing medical devices, including active implantable devices and in vitro diagnostic medical devices (IVDs). These devices must meet certain ‘General Safety and Performance Requirements’ (formerly ‘essential requirements’) before they can be put on the market in a member state. If a device is considered to meet these requirements a CE mark can be applied to it.

Once a device has a CE mark affixed in accordance with the relevant legislation, it can be put on the market anywhere in the EU/EEA. If the manufacturer is not established within the EU/EEA, they must appoint an ‘authorised representative’.


Two new Regulations came into force in Europe on 25 May 2017, one addresses medical devices (not including IVDs) and one which addresses IVDs. These are subject to transitional provisions, but will apply from 26 May 2020 and 26 May 2022, respectively.
The scope of the two Regulations has increased. For example, certain products with only an aesthetic or other non-medical use if their functioning and risk profile is similar to medical devices, will now be subject to the regime that applies to medical devices (e.g. non-corrective colour contact lenses, dermal and facial fillers). All tests that provide information on the predisposition to a medical condition or a disease, such as genetic tests, and tests that provide information to predict treatment response or reactions, such as companion diagnostics, will be IVDs.

The new Regulations introduce for medical devices and IVDs, amongst other measures:

- a new European database holding information about medical devices on the market (EUDAMED), which is expected to be operational in 2020
- a new Unique Device Identification (UDI) system
- greater supervision and strengthening of notified bodies
- a pre-market assessment procedure (‘Scrutiny-procedure’). Manufacturers and authorised representatives are required to have/have at their disposal a person responsible for regulatory compliance.
Manufacturers are required to collect and retain post-market clinical data as part of their obligation to assess potential safety risks.

Manufacturers are required to have measures in place to provide sufficient financial coverage in respect of their potential liability for defective devices.

Responsibilities and potential liabilities of authorised representatives have increased.

New supply chain obligations for importers and distributors.

Changes specific to medical devices, include:

- Tightening of the rules on clinical evaluations and clinical investigation and greater transparency of the outcome. For example, clinical investigations are more onerous and require a sponsor.

- New rules on reprocessing of single-use devices.

- New rules on the classification of standalone software, devices composed of substances intended to be introduced in the human body, and the inclusion of certain products with only an aesthetic or other non-medical purpose.
Changes specific to IVDs include:

- a new classification system
- tightening of rules on performance evaluation.

A further consideration for manufacturers is classification. Manufacturers will need to re-evaluate their product portfolios to assess the classification and compliance under the new Regulations, which may require significant financial investment.

While the increased regulatory burden on manufacturers may delay market access for innovative devices in Europe, the new Regulations are still likely to allow faster market access in Europe than in the US – although the change in the Regulations may have a significant impact for smaller US medical devices companies wishing to obtain a CE mark for their device.

**eHealth products as medical devices**

Over the past few years, eHealth has become one of the fastest growing markets. The global eHealth market is expected to double from US$159 billion in 2017 to US$308 billion by 2022\(^1\), with Europe taking a large share.

As eHealth takes off, an increasing number of devices are generating or capturing data relating to health and lifestyle.

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\(^1\) Grand View Research
Many eHealth products will constitute ‘medical devices’ within the meaning of the relevant EU and national legislation with the result that they will be subject to regulation.

Amongst other things, a medical device can be any instrument, apparatus, appliance, software, implant or other article whose intended purpose is the diagnosis, prevention, monitoring, treatment or alleviation of disease, and which does not achieve its principal action by pharmacological, immunological or metabolic means. Many eHealth devices or applications will fall into this definition and will thus be regulated under the medical devices legislation and will require CE marking before they can be put on the market.

Other than products expressly excluded from the scope of the medical device legislation, the key criteria that distinguishes a medical device from another type of product is (1) the manufacturer’s intended purpose and (2) mode of action. It does not matter that the medical device does not act directly on or in a human body.

Whether an eHealth product is a medical device or not will be determined by what the manufacturer intends the eHealth product to be used for. This ‘intended purpose’ is assessed with data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials. However, if the eHealth product ought to bear a CE mark as a medical device but the manufacturer has mistakenly decided it should not, the relevant national authorities can require the product to be taken off the market.
**Advanced therapy medicines**

Advanced therapy medicines are medicines based on genes and cells. For example, gene therapy, somatic cell therapy and tissue engineered products. These products are specifically regulated in Europe. All advanced therapy medicines intended for marketing in more than one EU/EEA member state are authorised centrally via the EMA and subject to monitoring once on the market.

**Biosimilars**

Biosimilars are biological medicinal products that are similar to an authorised biological product and which do not differ significantly from that product in terms of quality, safety and efficacy.

Many of the top selling drugs worldwide are now biologics and many companies are seeking to produce biosimilars to compete in these lucrative markets. Activity relating to biosimilars continues in Europe since the first biosimilars were authorised in 2006. Successfully bringing a biosimilar to market raises different challenges to small molecule generics and there are differences in the approach in the US and Europe. In particular, there are three broad guidelines that apply to all biosimilars in Europe: an ‘overarching’ guideline; a non-clinical and clinical issues guideline; and a quality issues guideline. These guidelines are supplemented by a number of product or class specific guidelines, also issued by the EMA.
3. Research and development
Funding and incentives

Europe is a world leader in research and development, with the highest absolute Dollar spend after the US and China. There are also a number of incentives for businesses outside Europe to conduct R&D activities on the continent, as well as various legal issues that may need to be considered.

R&D funding: Research and innovation in Europe are financially supported by the programme Horizon 2020, which will make nearly €80 billion of funding available between 2014 and 2020. €100 billion has been earmarked for its successor, Horizon Europe, which will run from 2021 to 2027. The key research areas that are funded are announced in two year work programmes, and individual calls for research proposals within these fields are published on an ongoing basis. Most calls require a consortium made up of at least three organisations from different countries, and a number of search services are available to help identify potential partners.

Incentives for life sciences research: Various regulatory incentives are available for life sciences investment in Europe. Fiscal benefits such as R&D tax credits are offered in some European countries, including the UK. Patent term extensions for medicinal products are possible, as are incentives to encourage the development of medicines for rare diseases (so-called ‘orphan drugs’), including research grants, reduced fees for regulatory authorisations, and increased protection from market competition (see Orphan Drugs, Chapter 2).
Key legal considerations

- **Competition law:** A research and development agreement is a ‘horizontal agreement’ within the scope of European competition or anti-trust law. Care should be taken to ensure that these agreements are drafted to comply with this legislation. Certain exemptions may apply, either in respect of an agreement individually or in respect of a category of agreements, by way of a block exemption regulation.

- **Intellectual property (IP):** Issues concerning ownership of IP commonly arise in the context of research collaborations, in particular with regard to patents. It is important that research partners record at the outset how patents arising out of the collaboration should be owned, and what rights they should have to use and exploit such patents. If this is not agreed, the default legal rules on patent ownership and exploitation will apply, which vary from country to country around Europe.

  Businesses will also need to have agreements in place to ensure that they own patent rights developed by their employees and independent consultants or contractors, as this is not automatically the case in many European countries.

- **Confidentiality/trade secrets:** Companies carrying out R&D activities must have appropriate confidentiality agreements in place from the outset to ensure that commercial confidentiality and potential intellectual property rights are protected. Confidentiality is often a key concern in collaborative projects, and the research
partners will need to include protections for technical information brought into the collaboration as well as information generated in the course of the collaboration. Where R&D is conducted with academic partners, these protections may need to be balanced against the academic collaborator’s obligations regarding the publication of results and the dissemination of ideas.

A new EU trade secret Directive\(^2\) took effect in 2018, offering strong remedies to trade secrets owners. To take advantage of the new law and remedies, holders of trade secrets will have to demonstrate the secrecy of the information in question, that it has commercial value and that reasonable steps have been taken to keep the information secret. This will mean reviewing existing procedures – as well as technological measures – to ensure that they are reasonable.

**Other sector-specific regulation:** Other legal issues may apply, depending on the nature of the R&D activities carried out, including the regulatory requirements governing clinical trials in the EU. European data protection law will apply in respect of research carried out with human subjects, and other regulatory areas may need to be considered for research involving the use of human tissues, animals or hazardous materials. Companies will also need to be aware of their obligations under European regulations to disclose research results, particularly in relation to clinical research.

\(^2\) Directive 2016/943
4. Clinical trials
At the date of writing, clinical trials in the EU are regulated by EU Directive\(^3\). This led to some variation in implementation in the EU/EEA member states. As a result, there was only partial harmonisation of the law relating to clinical trials. This created difficulties for pharmaceutical companies performing clinical trials in several countries.

A new Regulation is intended to solve these problems and set the global gold standard for transparency in clinical trials. It will bring a streamlined applications process, harmonised assessment procedure, a single portal for all clinical trials and simplified reporting procedures. The new Regulation will be directly enforceable in all EU/EEA countries. The Regulation is expected to become applicable during 2020 and only once the European Commission is satisfied that certain arrangements (including a EU wide clinical trials database) have been put in place.

Once the new Regulation comes into effect, the transition provisions included in it mean that the existing Directive may continue to apply to clinical trials where the clinical trial application was submitted before or within one year after the entry into force of the Regulation.

\(^3\) Directive 2001/20/EC.
Key considerations

Carrying out a clinical trial under the Directive:

- All clinical trials in Europe require a ‘sponsor’ – the individual or organisation responsible for the initiation, management and/or financing of the clinical trial.
- The sponsor is ultimately responsible for designing, conducting, recording and reporting the clinical trial in accordance with good clinical practice but may delegate its duties by written agreement.
- Prior to starting a clinical trial, the sponsor must:
  - obtain a favourable opinion from a relevant ethics committee that the anticipated benefit justifies the risks, and
  - submit a clinical trials authorisation application in the country(s) where the trial is to be carried out.
- All investigational medicinal products must be manufactured in accordance with good manufacturing practice (GMP).
The new Regulation will require that certain information collected by EU/EEA Member States in connection with the authorisation and supervision of clinical trials must be made publicly available, subject to certain limited exceptions such as the protection of personal data or commercial confidentiality.

Data protection and informed consent:

- The sponsor of the clinical trial is responsible for compliance with EU laws relating to data protection (see data protection below).

- A clinical trial may only be conducted if the trial subjects have given informed consent to their participation after being informed of the nature, significance, implications and risks of the clinical trial. Trial subjects can withdraw consent at any time.

- If personal data from a trial subject’s participation in the study is to be transferred outside the EU for any reason, the informed consent form provided to the trial subjects must unambiguously request this.
Presence in the EU/EEA:

- In relation to clinical trials of medicinal products, the sponsor of a trial must either be ‘established’ in the EU/EEA or appoint a ‘legal representative’ that is in the EU/EEA.

- In relation to medical devices, a company wishing to carry out a clinical investigation of a medical device in the EU/EEA must either be established there or appoint an ‘authorised representative’ that is.
5. Pricing
A large proportion of Europe’s pharmaceutical expenditure is covered by public payers, so the pricing and reimbursement measures adopted by national health authorities have a significant impact on whether most patients will have access to a new medicinal product.

National authorities in charge of pricing and reimbursement assess the added therapeutic value (ATV) of a medicine for the purpose of establishing a price. In particular, authorities will consider efficacy, safety and pharmaceutical quality of a medicinal product as well as its effectiveness, cost-effectiveness, budgetary impact, the severity of the disease and other factors.

Since ATV-based evaluations are the basis for national pharmaceutical pricing, the decision on whether or not a drug offers an additional benefit will determine its price. Pharmaceutical companies are currently required to carry out such assessments in each European country in order to determine additional pharmaceutical benefits.

This leads to two main problems: first, pharmaceutical companies as well as national authorities have to invest substantial time and money in the process for each country, since the current system does not permit the referencing of decisions in other EU Member States. Secondly, the decisions on a drug’s benefits may vary from country to country, which impacts upon subsequent national pricing.
Through the **external price referencing principle** that is applied by most European countries, national regulatory pricing influences pricing across borders. External price referencing means that the drug prices in the relevant countries are compared in order to set a national price or establish a basis for price negotiations with the relevant pharmaceutical company. As a result, price setting regimes for pharmaceuticals in Europe are very diverse.

The disparity in pricing regimes means that any pharmaceutical company launching a new product in Europe has to carefully consider where to market its product first.
6. Promotion, advertising and compliance
The promotion of prescription only medicines in Europe is regulated by Directive\textsuperscript{4}, as implemented into national law.

As a fundamental point, \textit{prescription-only medicines cannot be promoted to consumers in Europe}. Promotion is only permitted to healthcare professionals and relevant administrative staff (such as hospital finance directors).

\textbf{Over-the-counter medicines} may be advertised to consumers, but their promotion is subject to regulation under relevant national advertising codes (such as the CAP Code in the UK).

There is no prohibition on the promotion of medical devices to consumers in some European countries, although in practice most promotional activities for medical devices are aimed at healthcare professionals.

\textit{‘Promotion’} is broadly defined under European law. At its most basic, the mention of a medicine’s brand name and its indication comprises promotion. All promotional materials must be factual, balanced, up-to-date and accurate, and all claims made in them must be capable of substantiation by reference to data (typically the product’s SmPC or CE mark approval, or published papers or data).

Promotion of a medicine before the grant of a marketing authorisation in Europe is \textit{unlawful}, as is promotion of a medicine \textit{outside of its licensed indication}.

\textsuperscript{4} Directive 2001/83
The manner in which the advertising provisions of the Directive have been implemented into national law vary between countries. In some (the UK and Germany for example) there is a system of self-regulation under an industry association’s code of practice, such as the EFPIA and ABPI codes. All members of the respective associations are required to comply with the code of the association to which they have subscribed.

In France, any promotional document or information considered as such, on pharmaceuticals or on some medical devices, must be submitted for prior review by the French drug agency even if it is solely targeted at health professionals. Specific procedures imposed in France go beyond the Directive’s requirements. Advertising may also be subject to the control of specific divisions of the Ministry of Economy, as well as civil and commercial courts to which parties may lodge cases for unfair competition for example.

The promotion of pharmaceuticals and medical devices to healthcare professionals is also governed by general advertising law, as well as industry body codes of practice, such as the UK Association of British Healthcare Industries (ABHI) Code of Business Practice.

**MedTech Europe** – an alliance of European medical technology industry bodies has also introduced a code of practice that binds all members. Members include corporate
members and national associations (such as the Association of British HealthTech Industries).

Benefits made to healthcare professionals by pharmaceutical companies must be publicly disclosed in accordance with EFPIA’s Disclosure Code, which is broadly equivalent to the obligations imposed on US companies under the Sunshine Act.

Life sciences companies coming to Europe should pay particular attention to the French Sunshine Act, as well as to the specific anti-gift provisions applicable in France, prohibiting by principle the grant of benefits, financial or in kind granted to healthcare professionals.

The French Sunshine Act and the French anti-gift provisions, going beyond the EU principles, apply to all companies (European or not) manufacturing or distributing health products (whether or not they are marketed in France and including those that are not reimbursed) including: pharmaceuticals, medical devices, blood products, products based on human cells etc.

The French anti-gift provisions applicable to the health sector require prior declaration or prior authorisation to specific authorities in the case of agreements concluded with health professionals, invitation to conferences etc. The French Sunshine Act requires the disclosure on a public
website managed by the French Health Ministry of specific information on agreements concluded with, or of benefits in kind granted to, all categories of health professionals. This includes the disclosure of payments, and of reimbursement of costs, above 10 Euro.

The use of **social media by life sciences companies** has attracted considerable discussion and debate in recent years. Companies have found it challenging to balance the strict regulatory regime for advertising medicines with the attractive reach of social media channels and their potential for user generated content. The UK’s Prescription Medicines Code of Practice Authority has issued some guidance on the use of digital communications channels by pharmaceutical companies and highlighted, for example, that it is very difficult to see how Twitter could be used in a compliant manner to promote prescription-only medicines.
7. E-health and data protection
To date, most pharmaceutical companies have tended to restrict their use of social media channels to disease awareness campaigns and corporate matters, and healthcare professional only forums.

The pace of innovation in eHealth is nothing short of astonishing (see eHealth products as medical devices above) – covering mobile phone apps that provide direct medical support or connect to other medical devices, to patient monitoring devices, personal guidance systems, medication reminders provided by SMS and telemedicine provided wirelessly.

With respect to eHealth products that capture or generate data, the EU has adopted data privacy laws, which in the EU are referred to as laws on data protection, to ensure that this information is handled appropriately at all times. These include requirements that the data is lawfully obtained, used responsibly, kept securely and that relevant consents are collected.

Meanwhile, data protection is becoming an increasingly important area of compliance for businesses across and beyond the EU. The General Data Protection Regulation (GDPR) came into effect on 25 May 2018. It introduced new rights for individuals and an enhanced compliance burden on businesses, together with fines of up to 4% of annual global turnover for non-compliance. Businesses should be aware
that it has a wide territorial scope and can apply to businesses outside the EU which are processing the personal data of EU data subjects when offering them goods or services or monitoring their behaviour in the EU.

Non-compliance with the medical devices or privacy legislation can trigger negative PR, brand damage, regulator enforcement (including, prosecution and, in the case of serious breaches, fines) and civil claims.

**Personal Data Special (sensitive)**

**Personal Data**

Unlike the term ‘Personally Identifiable Information’ in North America, personal data in Europe means any information which relates to an identified or identifiable individual. The processing of genetic and biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation is prohibited unless the processing falls within an applicable exemption (for example the data subject has given explicit consent). Exemptions are contained in the GDPR itself but local member state laws (the Data Protection Act 2018 in the UK) may also be relevant.

Some key compliance points:

- Any activity where a business interacts with its users is likely to trigger some personal data collection.
Individuals must be given a range of information about the data collection in plain language, before the data is collected, including what data is collected, for what purpose and to whom and where in the world it might be sent. Transparency is essential.

There must be a permitted lawful basis for each processing operation and high risk processing should be subject to a Data Protection Impact Assessment before the processing begins.

Data security is vitally important. The more sensitive the personal data, the more stringently it must be protected.

A key element of GDPR compliance is being able to demonstrate compliance. This means businesses need to map their data and have appropriate records, systems and policies in place.

**Data protection fee**

In the UK, data controllers are required to pay an annual fee of £40, £60 or £2,900 (depending on turnover and number of staff). Exemptions may apply.

**Data exports to the USA**

EU data protection law prohibits the transfer of personal data to countries or territories outside the EEA unless they are considered to provide adequate protection. One of the ways
certain US organisations are able to demonstrate an adequate level of protection is to sign up to the EU-US Privacy Shield (which replaced the Safe Harbor scheme). Businesses may also choose to enter into Binding Corporate Rules or EU-approved Standard Contractual Clauses. Data exports from the EU to the USA are still under scrutiny by the EU so this is an area to keep an eye on if relevant.
8. Product liability
Across the European Union, medicines and medical devices are subject to the general product liability rules of the EU member states. An exception applies to Germany and, to a limited extent, Spain and a few other jurisdictions, whose national laws provide for particularly strict liability regimes that specifically apply to medicines. Within the European Union, the general product liability laws are based on:

- a **strict liability regime** (without fault) under the national laws of the member states implementing the EU Product Liability Directive 85/374/EC (the PL Directive), and
- supplemental **fault-based liability systems** (negligence) under the national laws of practically all EU member states.

Both liability regimes apply in parallel. While it is generally easier for a claimant to establish a claim under the strict liability regime of the PL Directive, fault-based liability (negligence) continues to play a role in cases where a claimant seeks to recover damages beyond the limitations and liability caps that apply under the PL Directive (see below).

‘**Product**’ is defined widely under the PL Directive, such that it will apply to almost all medicines and medical devices.

However, custom made drugs or devices do not typically fall within the scope of the PL Directive as it only covers products that have been industrially produced.
The ‘Producer’ is defined broadly to include:

- any person who, by putting his/her name, trade mark or other distinguishing feature on the product, presents himself/herself as the producer
- any importer who has imported the defective product, component or raw material into the European Union, and
- any supplier (eg the retailer, distributor or a wholesaler) if the producer cannot be identified.

There are three elements to establishing liability under the PL Directive: a product defect; damage; and a causal link between the two.

A product is deemed to be defective if it does not provide the safety that consumers generally are entitled to expect taking all of the circumstances into account, including the presentation of the product, its use that could be reasonably expected and the time when the product was put into circulation.

In a decision of March 2015, the Court of Justice of the European Union arguably significantly enlarged the concept of a ‘product defect’ under the PL Directive with regard to implantable medical devices. The court held that a potential defect in pacemakers and implantable cardioverter defibrillators could lead to the conclusion that all devices of
the same model/series are defective. In this case, the claimant only needed to prove that there was an increased number of device failures in the same batch or series and no longer needed to prove that the individual implant he or she had received suffered from a relevant defect.

However, in the class action against DePuy International Limited (a manufacturer of prosthetic hip implants), the English Court found in May 2018 that where a product has certain known underlying risks attached to its normal use, it will not be considered defective under local consumer protection legislation unless that risk is abnormal (and creates an abnormal potential for harm) when compared against other comparable products and the standard of safety expected by consumers. Further, in that case, the known inherent risk did not become a defect simply because of the number of recorded incidences of adverse reactions to the product (the risk of which was known). Whilst the DePuy decision will not be binding on other EU Member States, it will be persuasive for such courts when considering the meaning of a ‘defective’ product.

A key issue with medical devices is whether the way in which the product is presented, including the information and warnings given by the producer, provides consumers (and not only healthcare professionals) with adequate understanding of its inherent dangers.
Liability is generally not capped. However, EU Member States may set a limit for the total liability of a producer in the case of death or personal injury caused by identical items with the same defect.

The PL Directive contains a number of defences which a producer may seek to rely on, including:

- it did not put the product into circulation
- the defect is due to compliance of the product with mandatory regulations issued by the public authorities
- the state of scientific and technical knowledge at the time when the respective producer put the product into circulation was not such as to enable the existence of the defect to be discovered (the so called ‘state of the art’ defence).

Under both the PL Directive and in negligence, the liability of the producer can be limited if the producer can prove that the consumer’s negligence caused or contributed to the damage.

There is a limitation period under the PL Directive: three years starting from the date on which the claimant became aware or reasonably could have become aware of the damage and its cause, the defect and the identity of the producer. There is also a longstop date for liability: ten years from the date on which the product was put in to circulation.
While the substantive product liability laws of all EU Member States are largely harmonized under the PL Directive, the national procedural laws and court practice of the Member States which apply, among others, in product liability litigation can differ quite significantly, so local advice is essential.

The PL Directive is also under review by the European Commission particularly the extent to which it remains fit for purpose in its application to advancements in technology (which includes healthcare products).

**Artificial Intelligence (AI)**

A particular challenge in the area of life sciences products and research is the development of AI.

In April 2019, the European Commission published Ethics Guidelines for Trustworthy AI, after consultation with experts and representatives of member states. Using what the Commission call a ‘human-centric’ approach the Guidelines set out seven key requirements of AI, which include human agency and oversight, safety and data governance. These requirements will be subject to a piloting process to gather feedback and further development of policy in this area is expected.
9. The Unified Patent Court (UPC)
National and European patents

In Europe it is possible to obtain either a national patent or a European patent for an invention. National patents are granted through national government offices. European patents are applied for through the European Patent Office (EPO). A European patent application typically designates several, or all, of the European Patent Convention countries in which protection is sought (currently 38 countries). Once granted, the patent turns into a bundle of national rights – each providing national protection – registered in the national offices of the designated countries. Any dispute that arises concerning a national or European patent must proceed in the national court of the country of registration. However, all national designations of a European patent may be opposed centrally in the EPO, providing the opposition is filed within nine months of grant.

European and national patents provide exclusivity against exploitation of the product or process technology claimed in the patent by a third party. This exclusivity lasts for a period of twenty years from the filing date. This is a right of exclusivity to the claimed technology, but not a right to exploit it as such: a patent may fall within the scope of an earlier, third party owned patent, requiring permission from that third party before the later patented technology can be used.
A number of requirements must be satisfied for the claimed product or process technology to be eligible for patent protection in Europe. The technology must be: ‘novel’ (it is new); it must involve an ‘inventive step’ (it is non-obvious); it must also be capable of ‘industrial application’; and, it must not fall within the list of excluded subject matters (for example, stem cells obtained from human embryos directly, or indirectly, are unpatentable). Furthermore, the specification of the patent must be ‘sufficient’ – it must disclose the invention in a manner which is clear enough and complete enough for it to be performed by a person skilled in the technology concerned.
Supplementary Protection Certificates

EU law provides a system of supplementary protection certificates (SPCs) by which the term of protection for pharmaceutical products (and second medical uses of products) may be extended after patent expiry. An SPC may provide up to five years further monopoly protection for products that were covered by the expired patent.

In order to obtain an SPC, there are three key conditions that must first be satisfied:

▸ the product must be protected by a basic patent in force
▸ a valid authorisation to place the product on the market as a medicinal product must have been granted (this must be the first authorisation to place the product on the market as a medicinal product)
▸ the product must not already have been the subject of an SPC.

An exemption to SPC protection for manufacturing to supply non-EU markets; and stockpiling up to six months to supply the EU market after SPC expiry are expected to come into force in summer 2019. Transition periods will apply.
The Unitary Patent and Unified Patent Court

The Unified Patent Court (UPC) and the European patent having unitary effect (‘Unitary Patent’) were expected to come into full force in early to mid-2017, although this has been indefinitely delayed, first by the Brexit decision and then by a constitutional complaint filed in Germany. The UPC is intended to be a new pan-European court, to improve upon the existing system in which enforcement and revocation often requires parallel litigation in more than one national court. Together with the UPC, there will be a Unitary Patent, which is a single pan-European right protecting an invention, prohibiting anyone but the owner or their licensees from practising the invention in the participating countries.

The UPC will have exclusive jurisdiction for the enforcement or revocation of Unitary Patents. The decision resulting from such actions will have effect in all the participating countries. Likewise, it will be possible to enforce or revoke European patents in all their countries of registration by one decision of the UPC. However, during a transitional period of seven years, there is the choice whether to litigate European patents in the national courts or the UPC. During this period, European patents may also be opted-out of the UPC system altogether, for their entire duration.

National patents are unaffected by the UPC and will continue to be enforceable and revocable in the national courts only.
10. Branding and design rights
Registering your brand

Trade marks

In Europe it is possible to register company names, trading names, product/service names, brand names, logos and potentially also colours, shapes, motions and sounds (among other things) as trade marks. Registration can occur through the filing of a European Union Trade Mark (EUTM), which covers the whole of the EU, or a national trade mark in a single country/region. It is also possible to apply to register both EUTMs and national trade marks through the International trade mark system administered by WIPO. This can save time and cost if registered protection is required in more than one country/region worldwide.

Trade marks must be registered for specific goods and/or services. A trade mark registered for one area of use will not necessarily protect against third party use in other areas.

The EU operates a ‘first to file’ system and registration is not dependent on first having used the mark. Once registered, there is no obligation to use the trade mark for up to five years. However, if a trade mark is not put to genuine use for a continuous period of five years or more, the registration can be revoked. A benefit of the EUTM is that it can give indefinite protection in all Member States of the EU, without having to use it in all of them – use in even one country is potentially sufficient to maintain the registration.
It is also cheaper than filing nationally in all EU member states. However, the EU trade mark will not cover the UK if the UK leaves the EU (see Chapter 13. Brexit).

Life sciences companies wanting to set up business in the EU should **consider applying to register key trade marks at an early stage of planning**, well in advance of launch.

It is good practice to clear a new name or sign in the EU to make sure that its use will not infringe any prior rights. Failure to do so can be costly and embarrassing if you are forced to rebrand and pay compensation.

**Designs**

There are various types of design right protection in the EU, both registered and unregistered. The pan-EU registered design right can be particularly useful because it is quick and low cost to register, and can be maintained without any use requirement. There is also an unregistered pan-EU design right which lasts for three years but only protects against copying. The UK, uniquely, has an additional national only unregistered design right. On the whole, a registered design gives the owner a greater scope of protection than an unregistered design.
Protecting and enforcing non-traditional trade marks

Within the EU, non-traditional trade marks, such as colours and three-dimensional (3D) shape marks, are capable of being registered to protect the look of a product and its packaging. This can be particularly important in the pharmaceutical industry where consumers will often identify their medication by reference to how it looks.

In order to register a trade mark, it must be capable of distinguishing the goods or services of one undertaking from those of another. In addition, it must not consist exclusively of a shape or other characteristic which results from the nature of the goods themselves, is necessary to obtain a technical result, or gives substantial value to the goods.

Proving distinctiveness of these types of marks can be difficult and many applications fail. However, even if companies are unable to register these elements of their product or packaging as trade marks, they may be able to rely on passing off rights in the UK and unfair competition in other EU countries. Alternatively, consideration should be given to registered or unregistered design rights as a means to protect the appearance of products and their packaging.
European regulators do not have rules requiring manufacturers to use specific colours to indicate the presence of specific active ingredients. However, manufacturers are required to consider, for regulatory purposes, whether the use of a particular colour on a device would compromise patient safety. For example, manufacturers may need to consider whether the use of a certain colour for an inhaler is strongly associated in the minds of patients with a different clinical effect.

Parallel trade issues

Once goods are placed on the market in the EEA, the general rule is that they can be freely traded within the EEA, regardless of the presence of a trade mark on those goods. This is to preserve one of the fundamental principles of EU law: the free movement of goods within the EEA.

However, restrictions on free movement are permitted where there are “legitimate reasons...”. Particular problems can arise in this respect from repackaging. Repackaging of pharmaceutical goods – re-labelling, re-boxing, over-stickering – to enable them to be sold in a different EU Member State to the one in which they were originally marketed may provide a “legitimate reason” for opposing that further sale. This is because the repackaging affects the “specific subject matter” of a trade mark – changing the labelling of a product is liable to affect the guarantee of origin of the product that a trade mark is meant to provide.
Nonetheless, a trade mark proprietor may **not** stop the supply of re-packaged EEA products if:

- repackaging is necessary, and use of the trade mark constitutes artificial partitioning
- repackaging does not affect the original condition of the product
- the packaging clearly states:
  - who repackaged the product, and
  - the name of the manufacturer
- the presentation is not liable to damage the reputation of the trade mark and its proprietor, and
- the importer gives notice and, on demand from the trade mark owner, supplies a specimen of the repackaged product.
11. European structuring
– a checklist for life sciences companies coming to Europe
Any life sciences company wishing to do business in Europe needs to give careful consideration to how to structure its operations. This brief checklist highlights some of the key considerations:

- **Corporate structuring:** in which country should there be subsidiaries or branches of the company?
- Which country’s subsidiary should sit at the top of the European group of companies?
- **Tax structuring:** in which country should the intellectual property (IP) rights be situated and is there a preferential tax regime in that jurisdiction which can reduce the effective tax rate arising to the IP holding company in respect of income or gains arising from the licensing or use of those IP rights? The IP could be licensed to group companies depending on the preferred operational model of the group (which could, for instance, involve a separate entity in the group undertaking manufacturing of pharmaceutical products or devices from the entity which holds the IP).
- **Inter-company agreements:** what services or goods are required between group companies? For instance, this could include licensing of IP rights. Consideration should be given to appropriate pricing for the provision of such services or goods (as tax rules often require arm’s length pricing), the imposition of any withholding taxes on the payment of royalties and the value added tax (VAT) consequences arising from the payments.
First European foothold: In which country should the company first commence operations in Europe? Will this also be the first country to launch the product?

Pricing: In addition to considering where your first base in Europe should be, reference pricing applicable in Europe to pharmaceutical products should be taken into consideration: product launch in a country with a liberal price setting mechanism is preferable.
Sales model: will the company have subsidiaries or branches in each relevant country in Europe and sell directly? Will the company employ its own sales and marketing team, or use a CSO (contract sales organisation)? Or will distributors be used in some or all countries?

Regulatory and operational licences: which corporate entity will hold the marketing authorisation or CE mark? Which corporate entities will apply for other relevant operational licences, such as manufacturer’s importer’s licences, wholesale dealer’s licences or broker’s licences?

Intellectual property: which intellectual property rights should the company seek to secure in Europe? Which entity within the company’s group should hold those rights? Will the rights need to be licensed within the group?

See also the general checklist in the next chapter.
12. General considerations for companies doing business in Europe
In addition to the checklist in Chapter 11, you should also, as a minimum:

1. Remember that the law differs between European countries, although it is harmonised in some areas.

2. Plan ahead and take advice early.

3. Take immigration advice: this is key if you want to send employees to work in Europe – don’t take steps to set up without it.

4. Not forget that employment law is different in each European state – use local law contracts and take advice before terminating employees or changing their terms and conditions. Beware of the risks of using consultants.

5. Not grant stock options to employees in Europe without first taking specialist advice.

6. Consider protecting your trade marks early: a Community Trade Mark covers all EU states.

7. Decide on the appropriate method of trading in each European country early on, with appropriate advice.

8. Ensure you have adequate insurance in place to cover your operations in Europe.
9. **Protect the business** – consider a review of contractual terms and conditions, websites, privacy policies, anti-bribery and corruption policies and the like.

10. Get in touch with Taylor Wessing to discuss your plans and ask any questions you may have on the points covered in The Treatment!
13. Brexit
On 23 June 2016, Britain voted in a referendum to leave the European Union. Amongst other matters, this caused uncertainty about the impact on the regulatory regime governing the granting of marketing authorisation applications for medicinal products, as well as the CE marking system for medical devices. A number of other matters covered in the guide are also affected.

**Marketing authorisations**

As explained in Chapter 2, there are currently three routes through which a marketing authorisation can be obtained for a medicinal product under European law: the centralised procedure; the decentralised procedure; and the mutual recognition procedure. These give rise to marketing authorisations that take effect across the entire EU/EEA (under the centralised procedure) or, in the case of the decentralised and mutual recognition procedures, require cooperation between national competent agencies of the member states of the EU/EEA. In relation to medical devices, the CE marking regime will be governed by two EU Regulations when they replace the three core EU medical device Directives in accordance with the transitional arrangements.

The terms of the above legislation, governing marketing authorisations and medical device certification, will be implemented in UK law on the date of Brexit (currently
postponed to 31 October 2019) by virtue of the European Union (Withdrawal) Act 2018. This means that it will continue to be possible to authorise medicines and medical devices in the UK for the UK market after Brexit.

More complex, however, is the impact on mutual recognition of authorisations and CE marks between the UK and EU that is presently possible and which allows an authorisation or certification in just one country to take effect across the EU/EEA as a whole. If a trade deal is agreed between the UK and the EU, governing their future relationship, then it is expected that the current systems of mutual recognition will continue in broadly the same way, allowing, for example, a UK certified medical device to be sold on the EU/EEA market during the withdrawal transition period.

If no such deal is struck – a ‘no deal’ Brexit (in reality, moving to World Trade Organisation terms and such supplementary bilateral terms that can be agreed) – then authorisations and certifications will need to be obtained separately for the UK and the EU/EEA.

Further key issues arising in the event of no deal are:

- centrally authorised marketing authorisations will be ‘grandfathered’ onto the MHRA register as UK marketing authorisations
- marketing authorisation applications that are still progressing in the centralised procedure at the time of Brexit, must be transferred to the MHRA
generic, abridged applications will not be possible for drugs where the MHRA does not have access to the data underlying the original authorisation

marketing authorisation holders of ‘grandfathered’ marketing authorisations and QPs must be established in the UK for the purpose of market access in the UK market (subject to a grace period until the end of 2020)

the UK will continue to accept batch testing of human medicines carried out in countries named on a list set out by the MHRA (including the EU/EEA)

the UK will continue to recognise CE marking conducted by EU notified bodies post-Brexit, for a ‘time-limited’ period. However, the UK will be considered to be a ‘third country’ from exit day meaning certificates granted by notified bodies from the UK will no longer be valid in the EU/EEA and authorised representatives established in the UK will not be able to act in respect of products marketed in the EU/EEA

the MHRA has published details of the framework for medical devices to be sold in the UK in the event of a ‘no deal’ Brexit. All medical devices will need to be registered in the UK, through there are transition periods depending on the classification of the device

for an initial period, the UK will recognise exhaustion in the EU/EEA, allowing parallel trading of products into the UK from the EU/EEA to continue.

Note, however, that a number of these measures are currently only unilateral.
Patents

There will be no change to patenting in the UK or Europe as a whole (which is not regulated by the EU) and the supplementary protection certificate system will continue in the UK under UK law. As regards the UPC and Unitary Patent, the UK will explore whether it would be possible to remain within these systems in a ‘no deal’ scenario.

Clinical trials

It is expected that the new Clinical Trials Regulation (CTR) will be implemented in the UK so far as those parts of the Regulation that are within the UK’s control. UK clinical trial applications will continue to be authorised by the MHRA and ethics committees as they are now.

Horizon 2020

The UK government has guaranteed funding for all successful bids for EU projects submitted before the UK leaves the EU, including Horizon 2020 projects. This guarantee will cover the full duration of the projects.

Trade marks and designs after Brexit

On Brexit, EUTMs will no longer cover the UK. However, the UK government has said that all existing EUTM registrations will automatically be converted into comparable national UK trade mark registrations without any loss of priority/filing.
dates and for free. Those with EUTM applications pending on Brexit will be given a period of 9 months in which to apply for the same mark in the UK without any loss of priority/filing dates.

Accordingly, there is no real need to re-file any EUTMs in the UK pre-Brexit. The one exception is if UK protection is required urgently, perhaps for licensing or enforcement purposes. In this scenario, there might be a small advantage to applying for the mark in the UK (and EU) now as to avoid the inevitable delays at the UK Registry on Brexit.

Given that EUTMs that are registered as at Brexit will automatically be converted into comparable UK registrations, there is an obvious advantage to prosecuting pending EUTM applications expeditiously so that they register pre-Brexit. Consideration should be given as to whether any objections or oppositions against pending EUTMs can be resolved quickly and easily so that the mark registers in time.

The UK government has also said that it will continue to protect registered and unregistered pan-EU designs by the creation of comparable UK rights. In addition, the UK government intends to introduce a new unregistered UK design (comparable to the pan-EU unregistered design).

Those involved in actual or potential disputes concerning EUTMs, registered pan-EU designs or unregistered pan-EU designs should seek specialist advice on the potential impact
of Brexit. In particular, there might be significant strategic advantages to delaying or expediting actions depending on the particular facts of the case. There will also be strategic advantages to relying on a mixture of UK and non-UK prior rights in any actions.

Data exports from the EU to the UK after Brexit

The UK government has prioritised maintaining the free-flow of personal data between the EU and the UK after Brexit. The hope is that because the UK has already implemented the GDPR and has plans to keep its provisions in place after Brexit, an adequacy agreement (and preferably a bespoke arrangement) can be quickly agreed with the EU. Nothing formal will be agreed until after exit. In the event of a ‘no deal’ Brexit, the UK will continue to allow personal data to flow from the UK to the EEA, but EEA countries exporting personal data to the UK may need to look to one of the data transfer mechanisms like Binding Corporate Rules or Standard Contractual Clauses.
14. About Taylor Wessing
Taylor Wessing is a full-service international law firm, working with clients in the world’s most dynamic industries. We take a single-minded approach to advising our clients, helping them succeed by thinking innovatively about their business issues.

Our focus on the industries of tomorrow has enabled us to develop market-leading expertise in:

- Technology, Media and Communications
- Life Sciences
- Private Wealth
- Energy.

At Taylor Wessing we are proud of our reputation as a forward-thinking firm.

We support clients wherever they want to do business. Our 33 offices around the world are not token presences – they blend the best of local commercial, industry and cultural knowledge with international experience to provide proactive, integrated solution for our clients.
We are specialists in the life science sector. Our team includes lawyers with extensive industry experience and a deep understanding of the sector, having variously spent time working at a number of pharmaceutical and biotech companies, and having worked closely with a large number of life sciences clients over many years.

Taylor Wessing offers the capability of providing legal advice to life sciences companies through the full life cycle of their businesses. Taylor Wessing is widely regarded as one of the leading firms in providing a comprehensive legal service to the pharmaceutical, biotech, medical device, diagnostics and research tool sectors. This is based on our market leading practice across the full range of practice areas essential in providing services to the sector.
Our range of clients is diverse: from multi-national pharmaceutical companies to biotech start-ups, and it includes manufacturers of medical devices, diagnostic companies, research tool manufacturers and providers of healthcare services.

Our international life sciences group has extensive expertise advising across the full range of areas central to the business of our life science clients:

- fund formation, venture capital, M&A and capital markets
- regulatory and anti-trust advice
- licensing and partnering agreements
- collaboration and R&D agreements
- pharmaceutical and medical device patent litigation
- European strategy and set up.
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