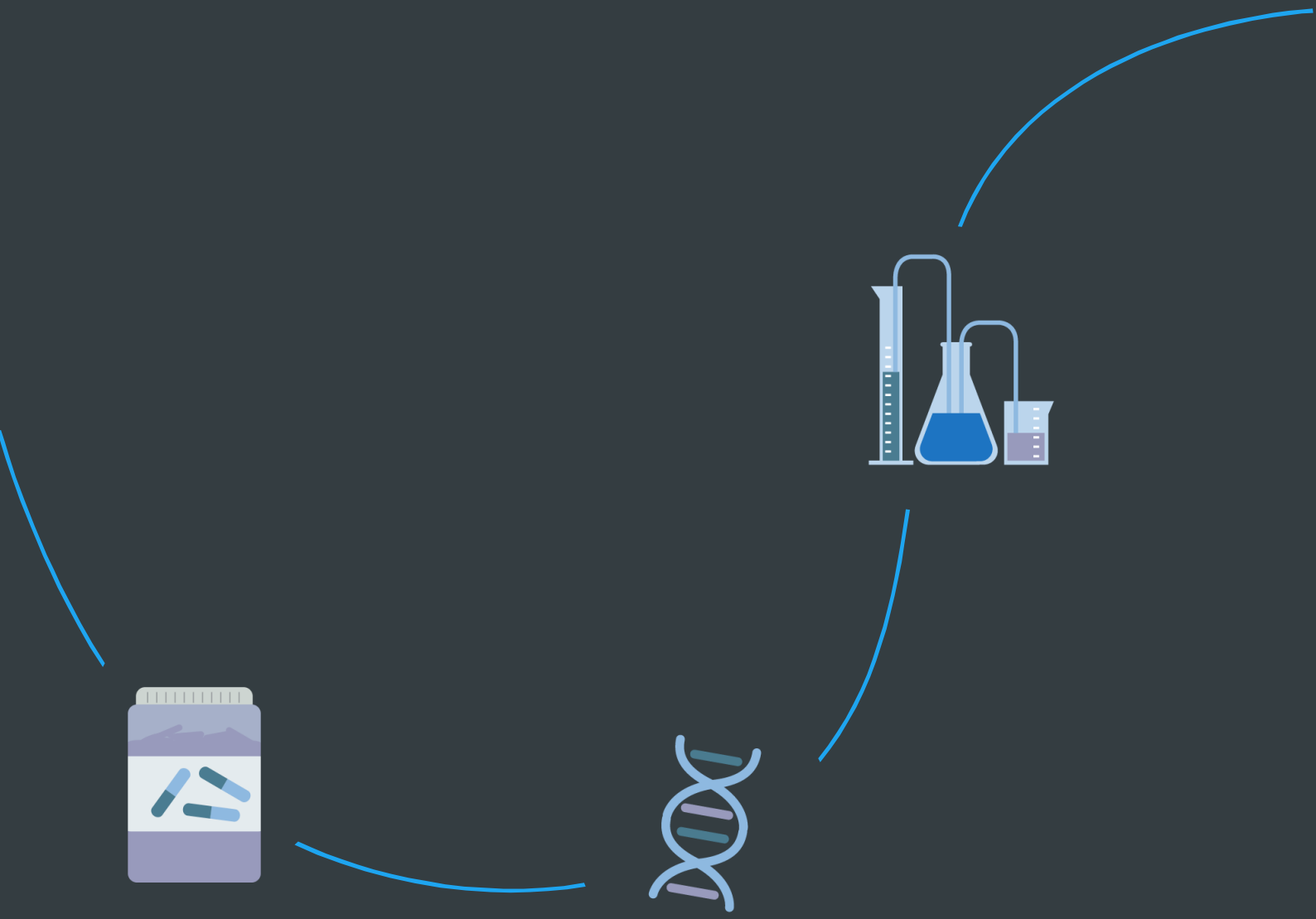
Bird & Bird

How to maintain your market authorisation after Brexit



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Protecting your business

Political agreement was reached in March 2018 on the broad terms of a transition period up to the end of December 2020. However, as matters stand, whether a final form of the withdrawal agreement and political declaration on the future UK-EU trading relationship can be agreed and approved before 29 March 2019 remains uncertain. As a result, the UK and the EU have been stepping up their preparation and information for preparing for a "No Deal" outcome where the UK leaves the EU abruptly and becomes a third country to the EU and EEA on the 30 March 2019.

The UK Government's desired "Brexit Deal" for medicines (as set out by the "Chequers' plan" and the follow-on MHRA announcement) involves continued close cooperation on medicine regulation including the desire to remain associated with the EMA as a non-voting member. The EU has not released an equivalent plan.

In the scenario of "No Deal", the UK Government has essentially proposed unilateral recognition of existing EU processes (as set out in its August and September technical notices) to minimise disruption, and has set up a Brexit Medicines Supply Contingency Planning Programme. A consultation (running to 1 November 2018) is seeking views as to how legislation and regulatory processes would have to be modified in a "No Deal" scenario. The consultation covers proposals on medicines, clinical trials and medical devices.

However, in a "No Deal" scenario, companies whose presence and activities are principally in the UK risk losing their **marketing authorisations** granted through the centralised procedure, unless action is taken to transfer key operations and activities to an EU Member State. Other rights, such as the EU support for small and medium enterprises, the "minor use minor species" status for veterinary medicines and the qualification as an orphan medicinal product may also be lost. Similar issues may arise in relation to **clinical trials** and **medical devices**.

Equally, companies should also consider UK activities and presence if they are currently based in the non-UK EU and EEA.

Despite the mutual interests of the UK and the EU in securing a negotiated outcome, given the uncertain political climate and past failure of the negotiations to make real progress, planning for the possibility of "No Deal" is now a necessity, given the limited time remaining until "Day 1".

If not already underway, companies should map out their action plan **as soon as possible**:

1. Which and how many of their rights will be lost on 30 March 2019 if no action is taken;

2. If they have entities in both the UK and the EU/EEA, which of these can take on the required responsibilities and activities such as being the authorisation holder, batch release site or holder of the pharmacovigilance system master file; and

3. What actions must be taken within what timeframe to prevent losing their rights, such as arranging the necessary variations, incorporations and physical relocation of certain business activities and persons.

"Very good cross-border knowledge of the law, paired with a deep understanding and knowledge of the pharmaceutical businesses."

Chambers Global, 2018

Our drive

Countering the challenges that Brexit poses for life sciences companies is at the core of what we do: **offering customised assistance to technology driven organisations** so they can focus their energy on developing cutting edge ideas and innovations. We operate in the same complex, dynamic international legal landscape as you.

Having this focus has enabled us to develop a unique combination of legal services for life sciences companies including the following:

1. having an in-depth understanding of the life sciences industry, its supply chains and the relevant competent authorities;
2. having vast experience with managing large-scale, international, complex projects;
3. being a full-service, top tier, international firm with a network, advisory role and reach into the legislative processes and its lawmakers.
4. provision of tailored cross-border teams of specialist lawyers from both the UK and the non-UK EU/EEA, essential for any Brexit project.

Our solution

Depending on the size of your company, the number of adjustments necessary to be fully prepared for Brexit and previous experience with such large projects, you may need a customised level of guidance from us.

We have therefore created various packages, including both legal solutions and project management, from which you can choose. For instance, we offer to analyse what market authorisations you hold and if any amendments are necessary to maintain their status. We can help in the variation process with the EMA and the UK Medicines & Healthcare Products Regulatory Agency. Should you need to set up a new subsidiary in the non-UK EU/EEA, we can help guide you in picking the country that is most suitable from a corporate, tax and logistical perspective. We can draft necessary agreements such as employment contracts and even assist your employees in finding housing or schooling for their children. We can also assist you with the measures you need to take with regard to your medical devices.

Challenges

There are several challenges in maintaining market authorisations in the UK and EU after Brexit. As a result of Brexit, life sciences companies whose activities are located only or mainly in either the UK or the non-UK EU/EEA are facing specific and potentially complex challenges. This not only relates to marketing authorisations, but for instance also for clinical trials and medical devices. We have mapped out these challenges in order to find you the best solutions.

Marketing Authorisations

- **Hard and short deadline**: assuming the UK will become a third country (non-EU/EEA) on 30 March 2019, the following activities, persons and registrations must be moved to a non-UK EU/EEA member state and be in place on 29 March 2019:
  - the holder of a **centrally authorised marketing authorisation;**
  - the **qualified person** responsible for pharmacovigilance;
  - the **Pharmacovigilance System Master File**;
  - the sponsor of an **orphan medicinal product**;
  - the sponsor or holder of a veterinary medicine with a "**minor use minor species**" status and that veterinary medicinal product itself;
  - **small and medium enterprises** looking to keep their SME support;

  Additionally, should the manufacturing site currently be located in the UK, an **authorised importer** and **site of batch control** must be **created** in the EU/EEA;

- **Loss of data obtained in UK**: bioequivalence studies which take place in the UK can only be used if the marketing authorisation is granted before 30 March 2019. Additionally, data obtained in the UK for traditional and well-established use applications can only be used if the data is from before 30 March 2019. Applications after 30 March 2019 for orphan drugs can also no longer count UK users in calculating the prevalence of the disease;

- **Establishing new entities**: EU law requires that marketing authorisation holders, qualified persons for pharmacovigilance and sponsors for orphan medicinal products are established in the EU or EEA. Should this currently not be the case and should your organisation not have establishments in the non-UK EU/EEA, these must be created prior to Brexit in order to maintain the marketing authorisations;

- **Standard of good manufacturing practice and control of the plant**: if the active substance is manufactured in the UK, a declaration from the UK competent authority is required stating that the standards used are equal to those in the EU/EEA;

- **Resetting of sunset clause**: if a pharmaceutical product is currently sold on the UK market only, the three year term within which the product must be placed on the non-UK EU/EEA market will start running again on 30 March 2019 from the date prior to 30 March 2019 on which the product was last put onto the UK market. If the product is not brought onto the EU/EEA market within three years thereafter, the authorisation will no longer be valid;

- **Bigger burden on the EMA**: in the months up to 30 March 2019 and likely also shortly thereafter, the EMA will not only have to deal with its relocation to their new Amsterdam offices (including the loss of higher staff numbers than initially anticipated) but also with an exceptionally large increase in variation requests and administrative changes from marketing authorisation holders. This may lead to delays in handling such requests despite the business continuity plan being implemented to maintain

essential public health and animal health activities.

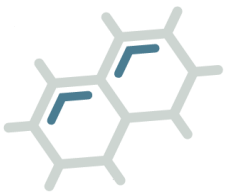
- **Bigger burden on UK government**: on the day of Brexit, the UK government is likely to lose its access to many of the benefits, resources and much of the knowledge now obtained via the EU system, such as the centralised procedure for marketing authorisations, the EU portal for clinical trials and the pharmacovigilance database. This will lead to an increased burden on the UK government, including the Medicines & Healthcare Products Regulatory Agency (MHRA), which may cause delays in important decision making processes for companies;
- **Bigger burden on life sciences companies**: specifically in the case of "No Deal", the administrative burden on companies will increase because regulatory requirements, for example clinical trial authorisations, pharmacovigilance and good manufacturing, laboratory and clinical practices, will be under a separate UK legal and regulatory framework despite the UK government's efforts to minimise disruption with unilateral recognition of EU processes;

Clinical Trials, Medical Devices and IP rights

- **Clinical Trials Regulation**: the new Clinical Trials Regulation EU No 536/2014 will not be in force in the EU at the time of Brexit ("No Deal" scenario). This may result in a divide between clinical trials legislation in the UK and the EU despite the UK Government's intention to align where possible when it does come into force in the EU;
- **Medical Devices**: after 29 March 2019, a manufacturer or importer established in the UK will no longer be an economic operator established in the Union and will become an importer under EU law. As a result of this, different rules apply. For instance, a non-EU manufacturer situated in the UK must appoint a sole authorised representative within the EU to be able to put the medical device on the market in the EU. Also, UK Notified Bodies will lose their status as EU Notified Bodies. This means that UK bodies can no longer perform conformity assessment tasks and that certificates granted by a UK Notified Body will lose their status as from the withdrawal date;

Protecting IP rights: In the draft withdrawal agreement, EU-wide IP rights (i.e. European Union trademarks (EUTMs), Registered Community designs (RCDs), unregistered community design rights (UCDs), database rights, and granted Community plant variety rights (CPVRs)) will continue to cover the UK during the transition period and will become "a comparable registered and enforceable intellectual property right in the UK" on 31 December 2020 "without any re-examination" (with the further practical details to be agreed).

In a "No Deal" scenario, the latest guidance from the UK Government maintains the same tone that existing rights will automatically become comparable rights and that it will be possible to file UK applications mirroring the pending EU applications (preserving the details and dates). There have not been any formal comments as regards the status of ongoing contentious issues. Given the uncertainty, to be prepared on 29 March 2019 should a smooth Brexit not arise, it would be prudent to be filing new UK applications (at least for the most important EU rights) and for new applications, filing UK applications in parallel with EU applications.



Actions

In the uncertain times relating to Brexit, it is important to be as organised as possible in order to proactively deal with any potential changes and manage risk. To that end, we have summarised key actions to be completed in order for you to maintain the relevant marketing authorisations and other important rights.

Reading guideline

Depending on the package you choose, we will update the actions set out below and include all your specifications and needs. The various letters correspond with the package possibilities which we offer on the next page.

Despite their best intentions, it is likely that dealing with both the EMA and the MHRA (as well as with Notified Bodies, in the case of medical devices) will be subject to delays, at least in the short term, due to the sudden increase in requests from the life sciences sector.

Timing	Action
2018 As soon as possible	Analyse your marketing authorisation portfolio, medical devices portfolio, IP rights and potential other EU and UK rights which may be lost on 30 March 2019 if no action is taken and set out what actions must be taken within what time frame to prevent losing those rights; If your organisation does not have any suitable corporations in the non-UK EU/EEA or in the UK, then decide where to incorporate. If these do exist, then decide what rights, activities and persons will be moved where e.g. where in the non-UK EU/EEA will the batch release site be placed if manufacturing takes place in the UK; Use a non-UK EU/EEA applicant to make requests for marketing authorisations and sponsors for orphan medicinal products if you have a non-UK EU/EEA entity; Choose if you want to appoint an EU authorised representative or move the entire medical device manufacturing facility. In the event of the latter, an additional actions list should be made; Establish or have established an EU/EEA-entity for the purpose of transferring the required persons, activities and rights; Transfer relevant rights, persons and activities to the new EU/EEA-entity, such as the qualified person responsible for pharmacovigilance; File an application for a slot to file the necessary variation(s) with EMA and file the variation(s). It can take more than 6 months before such variations are finalised; File request with the UK MHRA to obtain a declaration that GMP standards and control of plant standards are equivalent to those in the EU/EEA; Consider the establishment of a UK entity/put in place the UK legal presence requirements for UK marketing authorisations (Note: centralised MAs will be converted automatically to UK MAs in a “No Deal” scenario and the UK government will allow those without a current UK established MAH and QPPV until the end of 2020 to put these in place, but the MHRA will still require certain arrangements to be made in the meantime which will be consulted on, for example, access

	to relevant safety data.) Move medical device manufacturing site to the EU or appoint an EU authorised representative; Obtain certificate in relation to the relevant medical devices from an EU notified body; Obtain certificate from UK notified body and appoint UK authorised representative in relation to relevant medical device; File UK applications for existing European Union Trade Marks (EUTMs), Registered Community Designs (RCDs) and Community Plant Variety rights (CPVRs) (at least for most important rights)
2019 29 March	**Completion deadline** • Complete or have completed the transfer of any centralised marketing authorisation and other relevant rights, entities and persons from the UK-entity to an EU or EEA-entity; • Have appointed an EU notified Body instead of a UK notified body for medical devices from which the certificate relating to the relevant medical device is obtained; • Have moved the manufacturer of a medical device to the EU or appointed an EU authorised representative; • Have UK notified body and authorised representative for medical devices for the UK in place;
30 March	**UK is a country outside the European Union and European Economic Area**

Our approach to the project

We believe that large-scale and complex projects have unique challenges and complications. They also require a different type of lawyer – one who can focus on delivering successful outcomes and present their ideas in a matter that allows everyone involved to quickly understand them. Below we have set out various options from which you can pick and choose so we can discuss helping you where you need it most.

A. Analysis of your portfolio

Analysing of your portfolio includes, amongst other things, mapping out your current centrally authorised marketing authorisation(s), the location of your Pharmacovigilance Master System(s), your EUTMs, the status of your medical devices and the locations of your manufacturing site. The analysis also includes an action list with a timeline specified to your situation, showing what you must aim to do to make sure your business is prepared for 30 March 2019.

B. Solutions

After your portfolio, action list and timeline has been created, we can help provide the best solutions to the particular problems your company is faced with. For example, if your current marketing authorisation holder is situated in the UK, but you have multiple entities in the non-UK EU/EEA, we can help you decide what

entity would be best-suited to hold the marketing authorisation. Another possibility is that you do not have any entities in the non-UK EU/EEA and must incorporate a new entity. We can help you decide if you want to move (parts of) of your business from the UK to the non-UK EU/EEA. In case you do not yet have a cross-border group structure, we can assist in setting this up.

Changing the group structure for marketing medicinal products may also have important tax implications, which need to be taken into account in deciding on the proper structure and the position of the relevant entities within the group. This will also require new intra-group license agreements. If research and development has been done in the UK, but the resulting product should also be marketed in the non-UK EU/EEA by a different legal entity, transferability of the tax facilities should be taken into account in structuring the solution.

In all of the above situations, and many more of the challenges you may face, we offer a customised approach. Therefore, we adapt our services to the size of your organisation, the size and experience of your legal team and the extent issues you are faced with (e.g. an administrative or actual relocation of part or all of your business). This means that we can offer assistance on specific legal issues, offer a full legal assessment, or if required even counsel on the relevant social (e.g. quality of life) and business aspects (e.g. connectivity, employees, network) of the decisions you are faced with.

B.1	Administrative amendments	Advising what is the best way for your company to meet the administrative requirements and why. This is suitable for entities that have suitable business units both in the UK and the non-UK EU/EEA or that want to register their intellectual property rights in the UK.
B.2	Incorporation	Advising on where to incorporate if your organization does not have any suitable corporations in the non-UK EU/EEA or in the UK. This can include advice on the relative advantages of incorporating for tax and administrative reasons or for actual relocation.

C. Filings with the EMA and the MHRA

The most important implication of Brexit is the requirement for companies to obtain appropriately timed approval for their variations and administrative amendments from the EMA and where necessary the UK MHRA. This includes obtaining approval for changing the market authorisation holder, changing the qualified person for pharmacovigilance and batch release site.

This package option offers assistance in obtaining these approvals, keeps you up-to-date on the reference product of any relevant generic or hybrid marketing authorisation, helps you with the filings and keeps you updated on any related developments.

D. Incorporation

Should you currently not have entities both in the UK and the non-UK EU/EEA, it is likely that you will have to incorporate new entities to fully maintain your rights in the UK and the EU after Brexit. We understand that a lot must be taken into account in deciding where, how and to what extent to incorporate and move part of your business to another country. We have therefore developed three types of packages from which you can choose or combine, to assist you in this process. The first package contains legal assistance; the other two involve project management and draw on our third–party network to help you in the best way possible.

D.1	Legal management	This package offers you legal and management assistance in setting up and choosing how to incorporate your new entity and how to position it in the group structure. It includes, for example, legally incorporating your new entity or entities, legally transferring the relevant rights, persons and activities to the new entity and arrange the contracting work that comes with it.

D.2	Business management	This package assists you in finding the correct property for your new business unit, hiring employees and services, and offering any other practical service or assistance you may require. We draw on reliable partners in our third-party network in the EU and UK to assist you with these issues.
D.2	Social management	This package provides you with assistance in guiding your employees through a relocation, such as finding housing, language courses, or even a school for their children. We draw on reliable partners in our third-party network in the EU and UK to assist you to the extent necessary.

E. Intellectual Property Rights Audit

We offer an audit of your trade mark, design right and community plant variety rights portfolio which would also take into account any new developments in your commercial activities (which we will consider with you first) as well as any potential impact resulting from Brexit. This would also enable us to identify any redundancies and potential cost savings in the current portfolio and set out what rights it would be prudent to file as UK applications prior to Brexit.

Additionally, we can carry out an audit of your existing licensing and distribution agreements, as well as other relevant agreements, to advise on the potential risks (and potential opportunities) that Brexit will give for these agreements.

F. Medical Devices Audit

We offer an audit of your medical devices portfolio. This would also enable us to identify whether it would be better to move any manufacturing site from the UK to the EU or merely choose an EU authorised representative. We shall also set out what rights should likely have to be filed in the UK, such as choosing a UK notified body or authorised representative.

Our experience: Working with competent authorities

Our regulatory specialists have longstanding relationships within the UK and European competent authorities. We believe in using this knowledge and understanding of the healthcare industry to guide you through obtaining and maintaining your marketing authorisations, so you can keep focused on the day to day business and investing your time and energy in new innovations.

We have extensive experience of working at the interface of the pharmaceutical and healthcare industries and the associated regulatory bodies. We regularly work with EU and national competent authorities, such as the European Medicines Agency (EMA), the Pharmacovigilance Risk Assessment Committee (PRAC), the UK's Medicines & Healthcare products Regulatory Agency (MHRA), the Food Standards Agency AIFA and the Netherlands Inspectorate for Healthcare (IGZ) and Medicines Evaluation Board (CBG-MEB).

Our work in this context includes:

- advising our clients on their relationships with the regulatory authorities (e.g. accompanying clients to hearings and key meetings);
- advising the competent authority itself;
- obtaining and maintaining national or centralised marketing authorisations.

Several of our lawyers have been employed as legal advisers or inspectors for the EMA and national health authorities and/or notified bodies, while others have worked for these authorities as lawyers. This means we have a keen understanding of the processes and structure within the competent authorities and how they think and operate.

Our firm also has a strong legislative capability allowing our lawyers to actively participate in the rulemaking process on behalf of life sciences companies and/or the concerned sector organisations.

Our wider expertise in the life sciences sector covers the whole lifecycle of medicinal products (as well as medical devices), and we regularly advise on issues such as:

• pre-clinical and clinical data;	• product classification;
• clinical trials;	• pharmacovigilance issues;
• data exclusivity;	• inspections and audits;
• price fixing;	• interpretation of guidelines;
• reimbursement procedures;	• product liability issues and recalls.

Working with the EMA

- Direct contact (or preparing our client for direct contact) with the EMA in relation to:
  - scientific advice procedures (working with the client on scientific advice submissions and preparing for meetings with the EMA)
  - advising clients on means of interacting with EMA working parties as an "interested party"
  - general advice / EMA liaison in respect of various aspects of the MA procedure (including conditional authorisation/exceptional circumstances, paediatric investigation plans, orphan status, transfer of marketing authorisations, characteristics of legal entity able to act as an MAH, outcome of the (Invented) Name Review Group assessment and the "appeal" of scientific committee outcome).

- Successfully challenging the EMA's initial "legal notice" concerning interpretation of the requirements of Art 57 of the new PhV legislation - this was subsequently revised and republished.
- Advising a medical trade association on preparing for discussion with DG-SANCO concerning implications of the new PhV legislation in respect of MA variation, preparing another client for discussions with DG-SANCO regarding the nature of reference products (in respect of generic applications), and briefing another client for discussion with the ECDC agency in Sweden in relation to recommendations issued regarding vaccination programs.
- Our firm has also been involved with the EDQM / European Pharmacopoeia monograph procedure (preparation of filing -successful).

Working with the MHRA

- Direct contact (or preparing our client for direct contact) with the MHRA in relation to:
  - borderline issues, such as medicinal product vs. food health claims and medicinal product vs. medical device; and
  - policy and guideline interpretation questions;
- Our firm also has a vast experience in preparing for submissions and accompanying clients to pre-submission and scientific advice meetings.

Our experience: Incorporation projects

We have extensive experience of incorporating and structuring industry associations, not-for-profit companies and non-governmental entities.

The incorporation of a new entity requires consideration of a wide range of legal and commercial issues, and we field a multi-disciplinary team that combines, where required, substantive expertise in areas such as corporate, tax, employment, commercial, regulatory, real estate and finance. We have advised on the incorporation of new corporate vehicles in a diverse range of industry sectors, including healthcare, media, retail and sport.

New England Biolabs

We assisted US company New England Biolabs in the setting up of its French subsidiary. We provided a variety of advice in relation to corporate, tax, and employment issues.

Pixium Vision

Our international corporate team advised Pixium Vision, specialist in the development of bionic vision restoration systems, in the establishment of its German and Spanish operations. We advised on several issues relating to corporate, tax and employment aspects.

PRS for Music

We are currently advising PRS for music on its options to enable them to continue to operate in the EU post-Brexit. PRS currently operates via agents in Malta and Cyprus and is looking at a direct licensing strategy into other EU territories, such as Greece. We provided the client with a high level summary of the key pros/cons of establishing PRS in (i) Malta; (ii) Cyprus; and (iii) Ireland

London-based investment firm

We advised an investment firm with its registered office in London on the establishment of a branch in the Republic of Poland. This involved preparing and assembling relevant documentation, drafting resolutions and application forms.

Endemol Shine Group

We advised on the Endemol Shine Group's Brexit risk assessment plan, covering the actual or potential exposure of the group to legal risks as a result of Brexit in the following areas: contracts, regulation of audio-visual media services, Digital Single Market regulation, import tariffs and duties, immigration, social security, data protection and competition law.

Genpact (UK) Ltd

We advised this UK-based company on the establishment of their presence in Slovakia. This included advising on the due diligence process related to the acquisition of certain assets, suppliers 'contracts and employees in Slovakia for the purposes of outsourcing of certain services by the client's customer from the client. We also assisted with the preparation of the Asset Purchase and Employee Transfer Agreement regarding the assets, suppliers' contracts and employees to be acquired from its customer in Slovakia.

Our experience: Large scale cross-border project management

Bird & Bird is a truly international firm, organised around our clients. We match our passion and practical expertise to your vision to achieve real commercial advantage.

Everything is connected

With more than 1,200 lawyers and legal practitioners across a worldwide network of 29 offices, Bird & Bird specialises in delivering expertise across a full range of legal services.

UKMVO project

Bird & Bird has successfully led its cross-border UKMVO project and the corresponding implementation of the Falsified Medicines Directive (FMD). It involved:

- the incorporation of a significant new player in the UK pharmaceutical industry;
- the deployment of a substantial new repository IT system that must interoperate with a large number of third party systems; and the implementation of wide-ranging changes to the UK supply chain, with numerous stakeholders and hard deadline for completion, and within a very complex industry.

Deep industry knowledge

- Expertise in the legal and regulatory framework relating to each sector.
- A more practical, commercial approach, supported by advisors with decades of experience working in the relevant industries

International reach

Bird & Bird has offices in key business centres across the globe:

Europe: Amsterdam, Bratislava, Brussels, Budapest, Copenhagen, Düsseldorf, Frankfurt, The Hague, Hamburg, Helsinki, London, Luxembourg, Lyon, Madrid, Milan, Munich, Paris, Prague, Rome, Stockholm and Warsaw.

Middle East & Asia: Abu Dhabi, Beijing, Dubai, Hong Kong, Shanghai, Singapore and Sydney.

US: San Francisco

We were the first truly international firm with a presence in Denmark, Finland and Sweden, ideally positioning us to support companies looking to invest in the Nordic region. Additional focus groups for Africa, India, Japan and Russia, and extensive cooperation agreements with local firms increase our reach to other key jurisdictions.

Our new San Francisco office offers US-based life sciences companies who have to deal with Brexit in Europe a convenient point of access to coordinate their European work.

Excellence in client service

Bird & Bird operates as one truly international partnership: our goals, accounting and profit pool are all shared, as is our commitment to providing our clients with advice from the right lawyers, in the right locations. Our open and flexible business culture allows us to configure ourselves to respond as quickly and effectively as possible to the commercial pressures faced by our clients. Our priority is providing excellent client service, however they themselves define excellence.

Baseline

Thinking differently to resolve your compliance and transformation challenges.

Baseline is a consultancy service designed to deliver successful outcomes for organisations facing challenging commercial dilemmas with a legal element, including regulatory compliance and major technology-enabled change programmes.

Effectively addressing and resolving such dilemmas requires a multi-disciplinary approach, which Baseline provides by combining management consultancy skills and legal expertise. This uniquely integrated offering means Baseline is able to deliver an 'end-to-end' solution to an organisation's needs, delivering against both their change requirements and performance ambitions.

Baseline's work can be broadly categorised into two main work-streams:

Transformation Projects

Combining programme management, technical architecture, change management, commercial and legal skills to help navigate legal contracts and structuring while facilitating the stakeholder engagement, programme management and technical delivery that ultimately deliver a successful outcome.

Regulatory Compliance

Combining operational efficiency, process improvement, organisational design, change management and legal skills to deliver improved productivity and reduced costs alongside effective compliance and monitoring.

How we work

You'll find working with our experts refreshingly different. Baseline provides an agile and integrated approach aligned to your project deliverables and commercial objectives. We operate by a core set of principles with a focus on delivering:

- **An end-to-end solution:** a multi-disciplinary team combining the legal and consultancy expertise required to deliver a complete solution to the challenge you are facing.
- **Right to left thinking:** outcome orientated, working against deliverables that are driven by your definition of success.
- **Reduced complexity:** unambiguous advice that involves understanding how your business operates and delivering solutions that are simple and clear.
- **Sustainable change:** focus on employee engagement, co-designing solutions and rapid prototyping to design effective solutions delivering long-term change to your business.
- **Alignment of interests:** value-based fees that reflect the benefits we deliver, sharing both risks and rewards with you.

Contacts

We have a team with the skills you need and extensive experience of delivering in this complex project.

Sally Shorthose
Partner – The UK

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Sally has more than 25 years' experience working within and for life sciences and healthcare companies – including several years as Legal Director of Novartis UK – and specialises in providing a full range of transactional IP and regulatory advice in all sectors. She is the Editor of the EU Guide to Pharmaceutical Regulatory Law, a guide covering the regulatory requirements throughout the EU.

Wouter Pors
Partner – The Netherlands

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With more than 28 years of experience, Wouter focuses on patent litigation, which also helps him to keep in touch with innovative technology. He handles a wide range of patent disputes, in the life sciences sector with an increasing emphasis on biotech disputes, for both national and international clients. Wouter is also involved in numerous trademark and copyright litigation matters, including cases the European courts.

Next to IP work, he focuses on advice and disputes on life sciences regulatory issues.

Brent Springael
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Brent heads the Tax Group in the Brussels office, but also works from the Luxembourg office. His practice covers the full range of business-related tax matters, domestically and internationally, with a focus on specific industries including Life Sciences, Media and Tech & Comms. He also regularly advises non-profit associations on direct and indirect tax matters. However, intellectual property related tax matters are his main area of expertise.

Brent has written extensively on the practical implications of, amongst others, the Belgian and other European patent box regimes, the taxation of copyright income, royalty taxation, aircraft financing, holding company regimes, and non-profit association's tax rules in leading Belgian and international tax reviews. He is also a regular speaker at conferences on these topics and acts as guest lecturer in the IP Master Program at the University of Brussels.

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Partner – Baseline (UK)

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Edoardo is the Chief Executive of Baseline and has been a driving force behind the development of its approach to delivering to clients improved compliance while achieving significant cost savings.

Edoardo also serves as Partner and as a leader for UK team of Valeocon, where he has developed the Value Innovation practice, which concentrates on developing breakthrough ideas and partnerships for top-line growth. He is a certified consultant and instructor in the Lean Six Sigma approach to quality. He is one of a select few consultants to have supported GE Capital's European Six Sigma effort. In 2009 Edoardo was the recipient of the "Consulting and Training Excellence Award" given by the Italian business community as a recognition for the last 18 years' supporting his clients in their transformation journeys.

Mauro Turrini
Counsel - Italy

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Mauro has more than 15 years' experience advising clients on life sciences (medicinal products, medical devices, food supplements, cosmetics, plant protection products etc.) mainly in relation to regulatory and intellectual property issues such as clinical trials issues, authorisation procedures and market access issues.

Before joining us in 2008, Mauro worked for several medicines authorities, amongst which the European Medicines Agency (EMA). Whilst there, Mauro was responsible for providing a full range of pharmaceuticals advice, including generics and data exclusivity issues, biosimilars, parallel import and parallel distribution issues, orphan drugs, SMEs and transparency issues. Mauro was also a member of the EMA Innovation Task Force (ITF), which is the team specialised in product classification and borderline issues.

Sarah Faircliffe
Legal Director – The UK

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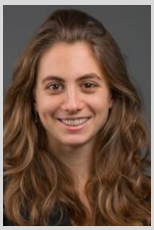
Working closely with Sally, Sarah specialises in European regulatory law, with a focus on medicinal products. She has a wealth of industry knowledge and a unique insight into the law and procedures concerning the regulation of medicines, having spent 10 years as Legal Adviser with the European Medicines Agency (EMA). During her time at the EMA, she advised on a wide range of regulatory topics, including orphan drugs, paediatrics and generics of centrally authorised products. She played a key role in the project to help the newest EU member states, joining in 2004, ensure that their national pharma legislation and procedures were in line with the EU requirements, and was closely involved in the drafting and implementation of many aspects of the revised pharmaceutical legislation.



Fenna Douwenga
Associate – The Netherlands

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Working closely with Wouter Pors, Fenna specialises in assisting and guiding life sciences and healthcare companies in both the area of regulatory law and intellectual property rights, in particular patents and licenses.

Eleanor Root
Partner – The UK

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Eleanor has a particular interest and focus on helping companies in the life sciences sector given her scientific background (BSc Cell Biology). Although she specialises in contentious patent matters, her experience extends more broadly including over a year in-house at a multinational pharmaceutical company where she managed multi-jurisdictional matters spanning commercial, regulatory and IP litigation, working closely with the different business functions to align legal and commercial strategies. With this skillset, Eleanor is particularly well placed to collaborate with colleagues in a multidisciplinary team to assist life sciences and healthcare companies throughout the business cycle of a product or service and achieve their commercial objectives.

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