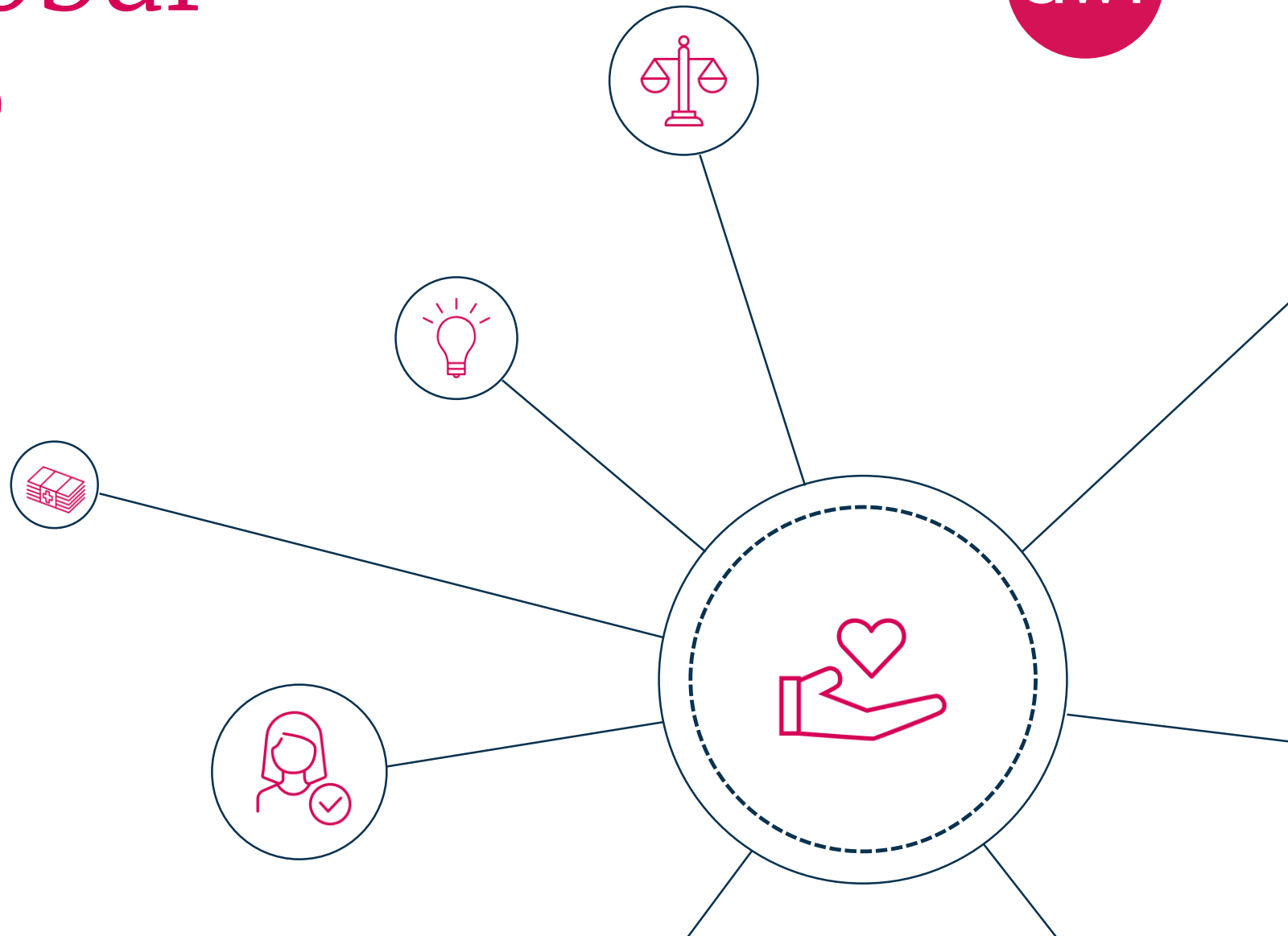
DWF – A global force in Life Sciences

DWF advises businesses involved in human, animal and plant research, it's technological development and commercialisation.



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Our expertise

The Global Team at DWF are aware of the multiple challenges being experienced in this fast moving sector. We have listened to our clients and understand that some clients only require support in one service area but others need our support across the range of services where law and life sciences intersect.

We offer the scope to 'pick and mix' legal advice sourced from the following areas;

- Product Liability
- Intellectual Property
- Healthcare
- Insurance
- Corporate M & A
- Venture Capital
- Research and Pharmacovigilance
- Data Protection
- Competition
- Company compliance
- Commercial compliance
- Regulatory
- Brexit

Expertise

1. Product Liability:

- Managing and mitigating the impact of an incident in the early stages of a crisis and designing suitable product recall programmes.
- Working with leading manufacturers, suppliers and their insurers to investigate, manage and mitigate product liability risks and claims, achieve compliance with product safety regulations whilst also helping to reduce their exposure to potential product liability claims.
- Assisting with compliance and corporate liability issues product liability claims and responding to and dealing with claims arising from alleged defects in products or clinical trials.
- Attending and representing manufacturers at Coroner's Inquests or Fatal Accident Inquiries.
- Supporting responses to regulatory investigations by authorities.

2. Intellectual property:

- Prior art searches, infringement, validity proceedings and prosecutions in relation to patents.
- IP infringement proceedings in relation to trade marks, copyright designs and models.
- Filing and management of IP rights.

3. Healthcare:

- Protocol and risk management advice – how medical interactions can be tailored and monitored to reduce the risk of near misses, and harm.
- Advice and representation with challenges faced when a medical intervention produces an adverse event and harm, including investigations (coronial, regulatory and criminal) and civil litigation.

Expertise

4. Insurance:

- Policy coverage advice and wording issues.
- Advising insurers in coverage disputes.
- Arbitrations arising from disputes.
- Supply chain challenges.

5. Corporate M&A and Venture Capital:

- Corporate M&A specifically tailored to Life Sciences issues including laboratory investments and acquisitions and disposals of contract development and manufacturing organisations.

6. Research and Pharmacovigilance:

- Contracts linked to development of clinical trials, observational studies
- Drafting of informed consent documents.
- Design of appropriate investigative protocols for legal framework of investigation.
- Advice for activities related to biomedical research, processes related to extraction, preservation, and application or implementation of human organs and tissues.
- Advice on meeting PV obligations.

Expertise

7. Data protection:

- Design and implementation of project adaptation so that activities with therapeutic, diagnostic or research purposes (such as treatments implemented by pharmaceutical laboratories, and the treatment of human biological samples -cells and tissues) will suitably follow protection-of-personal-data regulations.

8. Competition:

- All elements of Competition law including antitrust queries, potential abuses of dominant position etc.
- Advising on the scope of the notifications to the Competition Authorities related to potential acquisitions related to Life Sciences.

9. Company compliance:

- Internal procedures and protocols that facilitate compliance with advertising-field obligations.
- Review of all mediums of promotional materials produced by companies.
- Website evaluation (analysis of advertising content provided to the general public and health professionals, and review of requirements for making some content available to health professionals only).

Expertise

10. Commercial compliance:

- Review of consumer facing promotional materials for OTC produced by companies.
- Website evaluation (analysis of advertising content provided to the general public and health professionals, and review of requirements for making some content available to health professionals only).

11. Regulatory:

- Authorisation procedures; and medicine and medical device registration.
- Labelling and packaging of drugs and medical devices.
- Advice on borderline products.

12. Brexit:

- Advice relating to the impact of Brexit on regulations, contracts and supply chains.

Locations

United Kingdom & Ireland
Healthcare
Product Liability
Insurance

North America (Canada)
Healthcare
Product Liability

Germany
Corporate M&A
Product Liability
Commercial Compliance
Regulatory

Poland
Corporate M&A
Insurance

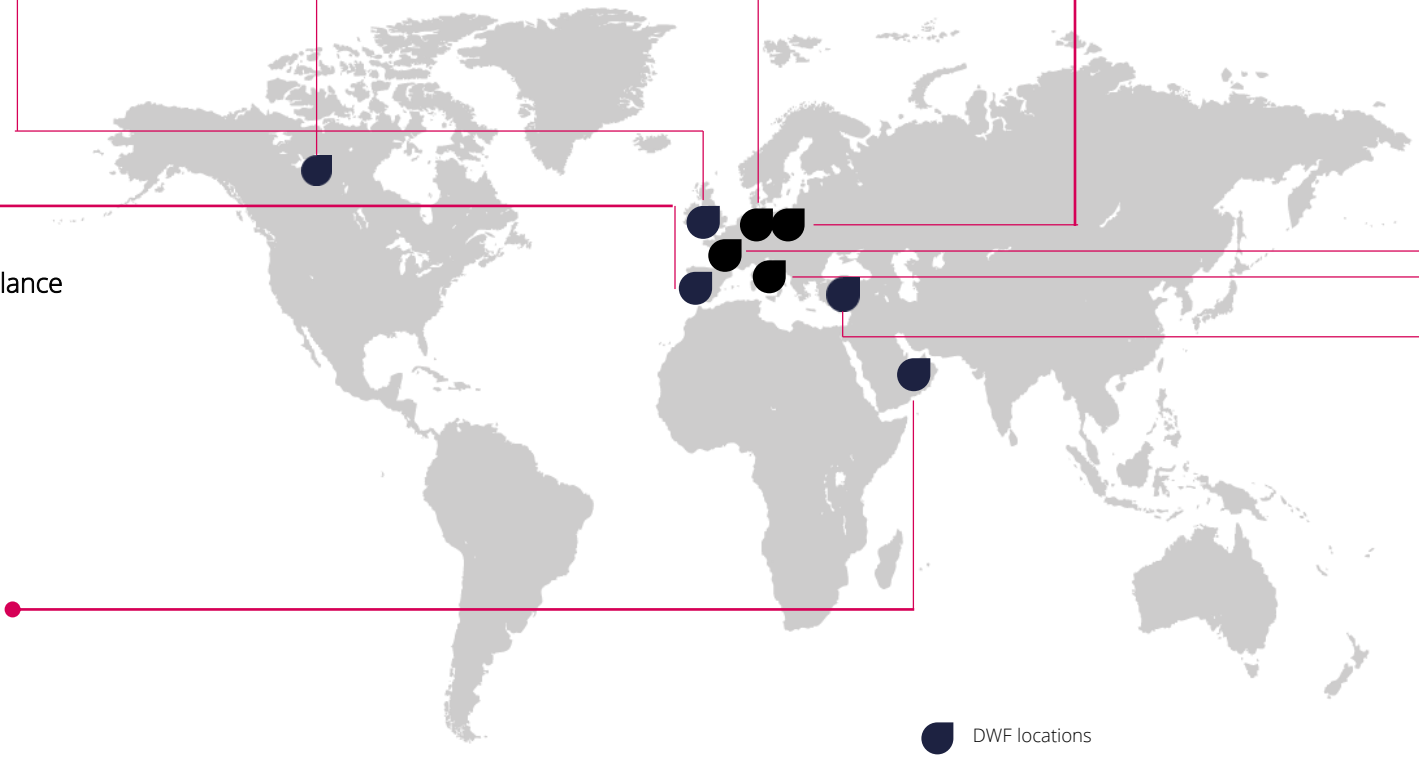
France
Insurance
Corporate M&A
Intellectual Property
Venture Capital.

Spain
Corporate M&A
Research and Pharmacovigilance
Product Liability

Italy
Insurance
Corporate M&A
Regulatory

Turkey
Intellectual Property
Product liability
Regulatory
Commercial compliance

Middle East (Qatar)
Venture Capital
Insurance
Regulatory



Examples of our experience

UK and Ireland

Healthcare:

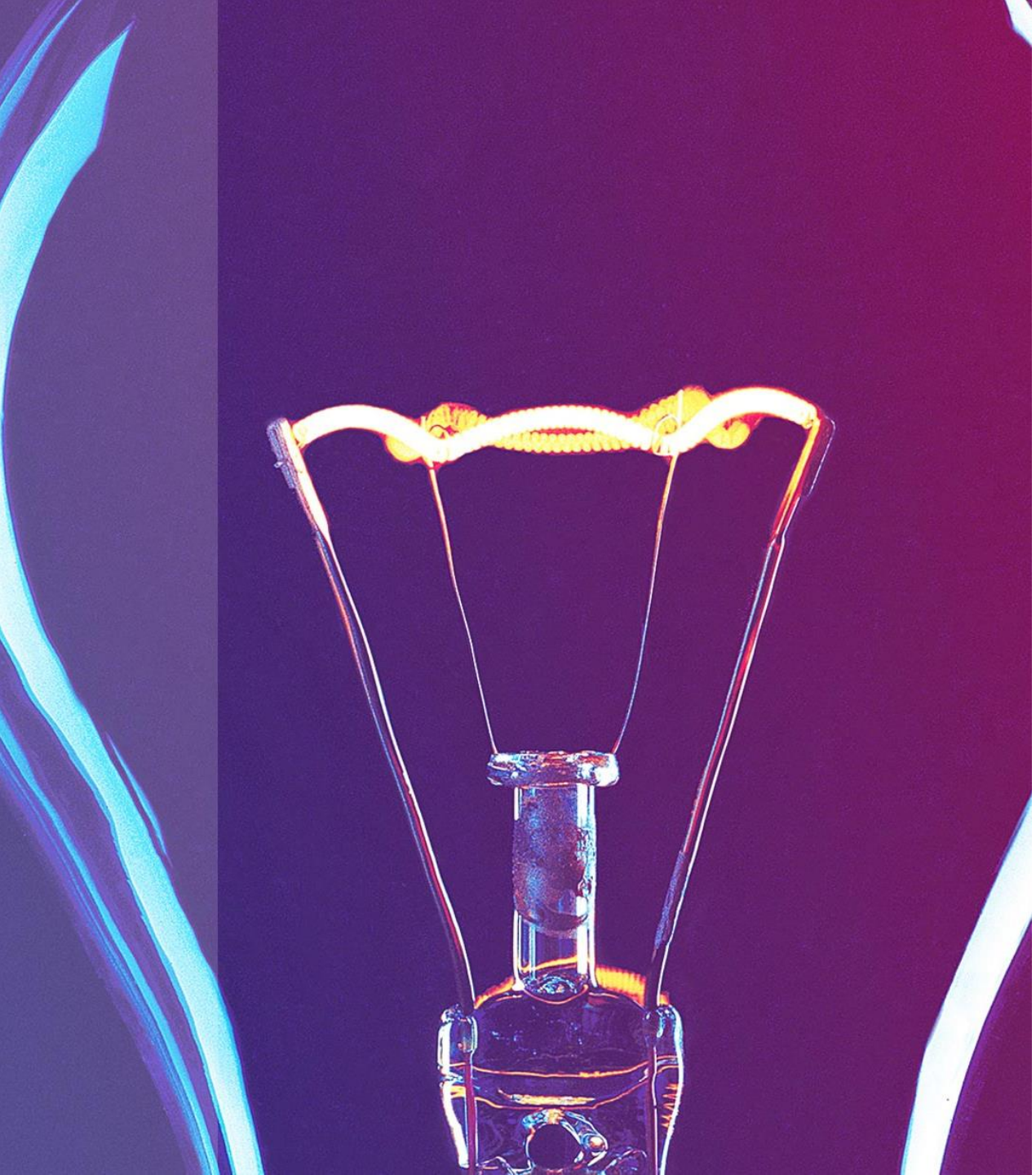
- Advising a private hospital. We assisted immediately following a maternity emergency, advising on duty of candour, staff support/training issues, structuring an internal investigation nominating an external expert review, and providing client funded counselling via an independent psychiatrist for the parents. An early admission of negligence assisted staff and the family in preparing for the inquest and accelerated the time line for resolution of the claim.
- Reducing the risk of prisoner self-harm and suicide. We assisted a client who had responsibility for the health of prisoners on behalf of the UK Government. The challenge was the incidence and risk of prisoner self-harm and suicide. Using anonymised and compliant data provided securely by the client, we designed a predictive model that would highlight individual prisoners at increased risk of self-harm by reference to the prisoner's individual demographics and profile. The tool deployed improved prisoner health and wellbeing and ultimately saved lives.
- Acting for a regulator in the health and social care sector in the defence of judicial review proceedings. This is a novel case concerning a challenge brought by a registrant in relation to their regulator's decision to postpone their fitness to practise procedures, pending the outcome of the registrant's disciplinary process at their NHS Trust. The application for permission for judicial review is robustly contested by the regulator. The potential implications of the case are wide reaching in that it may create a new precedent for regulators in the healthcare sector who might be forced to undertake their own processes, before the conclusion of any employment proceedings, when they relate to the same concerns.
- Acting on behalf of the General Optical Council (GOC) in a challenge brought by the Professional Standards Authority against a decision made by the GOC's Fitness to Practise Committee against a Registered Optometrist. The Optometrist was charged with gross negligence manslaughter in 2013 in connection with the death of a 7 year old patient from papilloedema (swelling of the optic nerve) following an eye examination with the Optometrist, where the condition was not picked up. The Optometrist's criminal conviction was overturned on appeal, but they were subject to Fitness to Practise Proceedings by the GOC in August. The conclusion of this was a 9-month suspension from practice. This decision was reviewed by the Professional Standards Authority and is being challenged by them in the High Court. This will be an important case for the optometry profession – arguably as important as Bawa-Garba was for doctors.

Examples of our experience

UK and Ireland

Product Liability:

- Advising a well known medical device manufacturer in the defence of their global product liability claims and product recall. One particular incident concerned a trial in Scotland following a fatality allegedly caused by a defect in the electrical wheelchair. (Peter Barnes)
- Advising a US insurer in respect of potential syringe drive defects which had led to a number of fatalities worldwide (Peter Barnes and Charlotte Kelly)
- Advising a large Japanese Manufacturing company on the warnings and guidance provided on their products with a view to minimising claims and increasing the defensibility of their products. (Peter Barnes and Charlotte Kelly)
- Acting for London Market insurers in respect of vaginal mesh advice and litigation (Peter Barnes and Charlotte Kelly)
- Advising US insurers in respect of liabilities arising from clinical trials stemming from a scheme with patients from Norway for the safety of a new gene injection for inherited retinal degeneration, Leber Congenital Amaurosis (LCA). (Peter Barnes and Charlotte Kelly)
- Advising global insurers in respect of contamination of pesticides and herbicides across millions of hectares of potato farms in South Africa and the liability issues arising out of the same. (Peter Barnes and Charlotte Kelly) Acting for a CRO and its insurers in a dispute with the Sponsor of a clinical trial involving a biosimilar. (John Groome)
- Advising the manufacturer of a product to treat the varroa virus in bees and its insurers in a dispute with co-operatives of bee keepers in Spain. (John Groome)



Examples of our experience

UK and Ireland

Insurance:

- Retained by two London market excess layers in respect of a potential coverage dispute with Purdue pursuant to multiple claims from authorities in the US alleging the drug OxyContin caused opioid addiction. (John Groome)
- Acting for three London market excess insurers in coverage disputes with the three largest pharmaceutical distributors in the USA. (John Groome)
- Acted for London market insurers in a USD 200 million coverage dispute in the Federal Court, Memphis arising from the bringing to market of a medical device without obtaining the appropriate FDA approval, with appointed expert David Kessler, the former Commissioner of the FDA. (John Groome)
- Advising insurers on coverage issues following the notification of an integrated occurrence involving the drug Tysabri, prescribed in the treatment of MS. (John Groome)
- Acting for US insurers in respect of coverage disputes arising medical device manufacturers in the UK and Europe (Peter Barnes Charlotte Kelly)
- Advising US insurers in respect of coverage implications of clinical trials (Peter Barnes)
- Advising London Market insurers in respect of cannabis products with Cannabidiol and without THC (Peter Barnes)
- Advising Insurers on underwriting issues surrounding trans vaginal and medical mesh exposure. (Charlotte Kelly)
- Advising Japanese Insurers in respect of implications of PFAs (Per-and polyfluorinated alkyl substances). (Peter Barnes Charlotte Kelly)

Examples of our experience

France

- **Insurance:** Act as counsel to a generic manufacturer of valproate products in procedure before French court and the national warranty fund (Dépakine). (Romain Dupeyré)
- **Corporate M&AV and Venture capital:** Assisting in the sale of an anapathe laboratory by their founding doctors to a company specialising in diagnosis and expertise in cancerology. (Pascale Gallien Vincent Lazimi, Marie-Noëlle Guilpain, Jessica Sellem)

  Advising Immutep, a French biotech company specialised in the development of T-cell response based immunotherapeutics against cancer and infectious diseases, two fund raisings. Including the fund raising led by Paris-based firm, Innoven Partenaires, involving a new investment from venture capital fund H2I, a specialist Biotech fund managed by Equitis. (Pascale Gallien, Vincent Maufront)
- **Intellectual property:** Assistance in connection with the setting up of an investment vehicle and incentive equity tools as well as in connection with the drafting and negotiating of an exclusive patent license agreement in the field of treatment of ophthalmic diseases. (Simon Christiaën, Pascale Gallien, Sawako Furusho)

Poland

- **Corporate M&A and Venture capital:** advising on a number of M&A transactions, including acquisition of insurance companies. (Anna Wietrzyńska-Ciołkowska)
- **Insurance:** drafting all documents necessary to start writing TPL insurance -product dedicated to pharmacies . (Paweł Stykowski)
- **Insurance:** representing insurance companies in disputes with clients and injured parties e.g. claims against hospitals for malpractice operations that went wrong. (Paweł Stykowski)

Examples of our experience

Italy

- **Insurance:** Reviewing, localization and translation of Life Sciences Risk Insurance Policy an drafting of IPIDs documents. March 2019. New Line (Lloyd's Insurance Company SA).
- **Regulatory:** Assisting in the relationships with AIFA (i.e. the Italian Medicines Agency) for the establishment of a network of medical sales representatives to perform co-promotion activities. November 2020. Consulcesi SA.
- **Corporate M&A and Venture capital:** Assisting in the opening of the first office of GW Pharmaceutical PLC in Italy. December 2019. GW Pharma S.r.l. (a subsidiary of GW Pharmaceutical PLC, UK listed company).

Spain

- **Corporate M&A and Venture capital:** Advising a major pharmaceutical company dedicated to the research, development, manufacture and commercialisation of pharmaceutical products and nutritional supplements on different operations. This included advising the client on their merger with another company in the same industry, creating the fifth largest pharmaceutical company in Spain. In this case, unusually, a small listed company merged with a large unlisted company. This meant that we had to rely on our experience in operations involving listed companies to obtain authorisation from the CNMV (Comisión Nacional del Mercado de Valores, the Spanish Securities and Exchange Commission). This deal was recognised as the best corporate transaction of the year by the Association for Corporate Growth (ACG). We also advised the client on the acquisition of a portfolio of pharmaceuticals and nutraceuticals for arthritis treatments from another Spanish pharmaceutical company.
- **Research and Pharmacovigilance**: Advising a Spain-based start-up specialised in life sciences (developer of a new generation catheter to safely and efficiently perform mechanical thrombectomies for treating acute ischemic strokes) on closing a EUR 20m funding round, led and subscribed by a set of prestigious investors. The received funds will be used to cover the costs associated with a clinical study in Europe and the United States to validate a medical device.
- **Intellectual Property:** Advising a research centre specialised in nanotechnology, whose aim is to build neuroelectronic interfaces to cure brain disorders. The client is developing a medical device and is interested in supporting a clinical trial that will be conducted by the University of Manchester. For these purposes the parties have been negotiating a collaboration for the support of an investigator-initiated clinical trial. Providing legal advice in drafting and negotiating the collaboration agreement

Examples of our experience

Turkey

- **Intellectual Property, Product liability, Regulatory and Commercial compliance:** Leading a team of 10 lawyers experienced in LS industry with all sub-industries (pharmaceuticals &biotechnology, medical devices, food & food supplements, cosmetics, veterinary products). Serving many clients on a retainer basis along with others from the Turkish LS industry.
- **Regulatory:** Board Member of Turkish Clinical Trials Association and Founding Board Member of Association of Companies Focused on Rare Diseases (NAFIDER).

UAE / Qatar

- **Regulatory:** Acting for Riyad Bank (as agent) in relation to SAR 164,215,000 murabaha financing facility provided by the Ministry of Finance, Kingdom of Saudi Arabia to Middle East Healthcare Company.
- **Insurance:** Advising public liability insurers on coverage for claims in Dubai (litigated and non litigated) arising from The Address Downtown Dubai Hotel fore. Also advising on contribution issues with related liability policy. Between 2016 – 2020. (Brian Boahene)
- **Insurance:** Advising Builder's Risk insurers on the quantum of a claim by the insured in the Dubai courts following total loss of luxury yacht under construction. Securing landmark judgment holding that the policy indemnity basis was limit of liability rather than agreed value. Between 2016 – 2018. (Brian Boahene)

Examples of our experience

Australia

- **Healthcare:** Advising Healthcare and Insurance/Medical Negligence for Queensland Government Insurance Fund (Queensland Health - equivalent of NHS). Advising regional Queensland hospitals (e.g. Darling Downs HHS and Townsville HHS), on all aspects of regulatory and safety protocols for staff and patients, e.g. assaults on staff by patients. Defending negligence claims made against doctors and other health service providers within Hospitals and Health Services - comprising circa 100 old and new claims, bringing in circa $800,000 per annum, and growing at about 10% a year. Coronial - representing Hospitals (e.g. Gold Coast HHS in 2019 re death in custody).

Canada

- **Healthcare:** Paramedics who were part of a larger medical malpractice case, were alleged to be liable for improperly diagnosing a stroke at the time of assessment on scene. As the issues relating to liability were distinct from the other medical professionals involved, the parties agreed to an arbitration of the discreet issue relating to the paramedics, which resulted in a finding of non liability. The damages had been agreed upon prior to the arbitration as they were not in dispute.

  Acting for a pharmacist who incorrectly dispensed an ER physician's prescription. The hospital staff learned that the patient was being provided with 8 instead of 3 doses of medication per day and alerted the pharmacist who confirmed that the dosage was incorrect. The pharmacist advised the patient of the discrepancy. Despite this action, the patient proceeded to make a complaint claiming that the correct dosage was not notified. The pharmacist was able to establish through documentary evidence that the proper dosage had been prescribed and that the patient was made aware - no further action was taken

- **Product Liability:** A hospital pursued damages for the failure of an air filtration system that was improperly installed and inspected which required the evacuation of a hospital ward as a result of the failure of the system. Although the matter was litigated and trial was scheduled, ultimately a settlement took place following the production of an expert report that clearly outlined the negligent actions of both the manufacturer and the repair company, thus permitting the hospital to recover a significant amount of the financial losses it sustained as a result of the failed air filtration system.

Examples of our experience

Germany:

- **Corporate and M&A and Venture capital:**

  Corporate: Long-term corporate housekeeping for pharmaceutical company in different countries.

  M&A: Advising and representing the owner of a German manufacturer of clinical trials in the sale of the business to US competitor

- **Regulatory:** Unfair Competition: Long-standing representation of a pharmaceutical company in numerous court proceedings with competitors and associations with legal standing for unfair competition claims.
- **Product Liability:** Advising and representing insurance company in product liability proceeding with regard to medical device.
- **Commercial compliance :** Advising a manufacturer of medical products on the marketing campaign for market entry in Germany. Advising on competition law and medical product advertising law.

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