

**Helping you
achieve your goals**

Our global vaccines and
vaccination law capabilities



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As the roll-out of COVID-19 vaccination continues at pace around the world, interest in vaccines is at an all-time high. While an effective vaccine can take many years to develop, the pressure of the global pandemic has led to unprecedented collaboration and within 12 months of the first reported cases of COVID-19 in Wuhan, China, in December 2019, there were over 200 vaccine candidates for COVID-19 in development.

The World Health Organization believes that the success of COVID-19 vaccines in stopping the pandemic depends upon the effectiveness of the vaccines, how quickly they are approved, manufactured, delivered and how many people get vaccinated.

The process of developing, testing, manufacturing, marketing and transporting vaccines of any kind raises many areas of specialist law. IP protection, clinical trials, authorization, pharmacovigilance, EU joint and advance procurement agreements, domestic price and reimbursement proceedings, liability and large-scale manufacture and distribution are only some of the challenges companies must navigate when delivering a successful vaccine.

The devastating impact of the COVID-19 pandemic has also raised legal questions about the role that government, health authorities and employers will play in the roll-out of vaccines.

Eversheds Sutherland's work with a variety of global biotech and life science sector clients enables us to provide tailored advice which goes way beyond the law firm experience. Our global life sciences and healthcare sector team includes many attorneys with in-house experience in pharmaceutical companies, who have worked as scientists in the biotech sector, as pharmacists, or for the regulatory bodies and who have university degrees in biochemistry, chemistry, physics and other sciences.

Eversheds Sutherland has expertise in many areas of vaccines and vaccination law and is ideally placed to guide you through the range of issues that you may face whether as a developer or manufacturer of vaccine, related supply chain issues or as an employer seeking advice about what role vaccination can play in returning your workforce to workplaces around the world.



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Competition and market access

While all countries need vaccines, not all countries have the means to produce them. Our Global Competition, EU and Trade Team advises on all aspects of supply chain and distribution strategy for vaccines, the active ingredients required to produce them and the goods required to move them around the world and administer them (including vials, syringes, cold boxes, and freezers).

This can include early stage advice around possible collaboration, or the creation of joint ventures or other partnerships amongst competitors; as well as advice on the creation of distribution networks, including selective distribution. We also have experience advising on specific elements of distribution strategy, including so-called “most favored nation” or parity clauses; and resale price maintenance risks.

Eversheds Sutherland’s Global Competition Team also regularly advises on the competition law risks in pricing strategies, including discount and bonus schemes and can work with you to help you make crucial, strategic decisions quickly and efficiently. In addition, our team can provide assistance on complex investigations by the competition authorities, including dealing with requests for information, challenging sanction decisions, as well as dealing with stand-alone or follow-on actions by individuals, public bodies or consumer associations against alleged anti-competitive conduct.



Recent examples of our work includes advising:

- a leading vaccine manufacturer in the Italian Competition Authority’s investigation into alleged collusion in the context of tenders run by the Piedmont Local Health Company for the supply of vaccines for seasonal flu
- a global contract manufacturer in the biopharmaceutical industry in relation to its participation in the UK Government’s COVID-19 taskforces for vaccine manufacture and supply chain
- a global pharmaceutical manufacturer in the Federal Antimonopoly Service of Russia’s investigation regarding the interchangeability of vaccines
- an international pharmaceutical company on public procurement matters relating to medicines and the application of national protectionist rules by the public customer, receiving a clarification from the FAS and Ministry of Trade of Russia that limits restrictive application of protective regulations
- a pharmaceutical manufacturer in relation to a pricing investigation
- an international manufacturer of healthcare related products on dawn raids, including conducting ‘mock’ dawn raids





Data privacy

The development of technology has enabled the creation, collection and retention of more data.

It has also resulted in Artificial Intelligence or AI developments, as well as advanced machine and deep learning. Bringing together these elements creates new opportunities for pharma which carry enormous potential value for the sector and society. These opportunities must be carefully managed against the risks and demands posed by data privacy laws as they spread and mature around the world, requiring ever greater transparency, accountability and controls on data use, to counteract potentially harmful and intrusive technology impacts.

Our Global Data Privacy Team has huge experience helping clients to utilize new technologies and products, facilitate data sharing and expand data uses, including to enable research and analysis, in ways which enable them to comply with their data privacy obligations. Our Team has worked over many years with numerous clients in the sector assisting them with these opportunities, combining that with a deep understanding of data related technology from work in the TMT sector and about data gathering and research issues from our work across the education and charities fields.

Our wealth of experience has given us an understanding not just of the law in this area, but also of the way in which to approach its application practically, to mitigate risks and support improved compliance.



Recent examples of our work includes advising:

- a large Scandinavian client on their UK proposals around collection of vaccinations data for reporting, lobbying and health and safety purposes, including in relation to transparency and accountability, the lawful basis for the proposals and related legal and ethical considerations
- a leading international vaccine manufacturer on data protection issues and the actions to be taken to comply with the Data Protection Code of Ethics issued by Farmaindustria (the National Trade Association of the Spanish based pharmaceutical industry)
- a leading international vaccine manufacturer on Joint Controller Agreements and Inter-Company Data Processing and Transfer Agreements

In addition, we have helped clients with data privacy compliance and strategy in relation to some of the largest health research programs in their country, including advising on and dealing with:

- data anonymization and pseudonymisation issues
- material transfer agreements
- collaboration, partnership and data sharing agreements
- privacy information and consents



Disputes

The COVID-19 pandemic has created a unique landscape for disputes where national authorities competing for vaccine volumes may utilize non-contractual rights to leverage their contractual position.

Additional challenges have been posed by the rapid scale up of manufacturing capacity for COVID-19 vaccine production, creating constraints on the manufacture of other medicines and vaccines which may affect the ability to deliver on contractual commitments.



Recent examples of our work includes advising:

- a major pharmaceutical company based in Italy to successfully negotiate the termination of a suite of agreements relating to the development and supply of particular vaccines in Denmark
- and defending a leading vaccines manufacturers in disputes with national governments, regional Health Services and regulatory agencies related to vaccines authorization, price, reimbursement, public procurement and other regulatory issues
- and defending at court leading vaccines international manufacturer in disputes with the Public Administration, NHS and competitors related to a meningococcal vaccine
- and defending at court a leading vaccines manufacturer in disputes related to public procurement of a pneumococcal vaccine
- a leading vaccines manufacturer in a dispute against various Health Regional Authorities related with the purchase of vaccines for children included in the National Vaccines Program of the Spanish Government. The case is currently at the Supreme Court
- and defending a procurement challenge relating to a core component of the UK government's COVID-19 response brought by an unsuccessful supplier, in urgent High Court and judicial review proceedings
- global medicines companies on compensation claims brought in relation to side effects and adverse reactions, allegedly linked to particular medicines or treatments

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Combination of real litigation expertise with practical assessment of what really matters and what the underlying dynamics and risks of the case actually are.

UK Biocentre Ltd

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Employment

There are still many questions as to whether employers can require employees to be vaccinated, whether vaccinations are necessary to maintain a safe place of work and how to respond to staff who refuse to be vaccinated.

Many employers are also considering issues around access to vaccination for their workforce. Can and should they take steps to arrange vaccination for their workers in countries where vaccines are not expected to be widely available for some years to come? Our Global Employment Team will work with you to understand the challenges faced within this area.



Recent examples of our work includes advising:

- multiple employers around the globe and across a range of sectors on the role that vaccination can play in returning workers to the workplace, including whether employers can require or encourage staff to be vaccinated. Our advice has covered employment duties, health and safety law, data privacy, and potential discrimination and consultation issues
- and conducting a comparative analysis highlighting the different issues that employers face in different countries when seeking to implement a global approach to COVID-19 testing and/or vaccination
- and developing workplace policies and procedures for employers seeking to conduct COVID-19 testing and/or mandate vaccination of workers



IP protection

Our Global IP Team can work with you to spot critical issues early and to reach strategically sound and cost-effective solutions.

Our lawyers understand that asserting IP and defending against allegations of infringement are a critical part of an overall competitive strategy – the stakes are high for both sides in a dispute. A large number of our IP attorneys hold specialized and advanced degrees in chemistry, molecular genetics, medicine, chemical engineering, electrical engineering, computer engineering, mechanical engineering, or other disciplines, providing invaluable background and insight into the technology and issues in dispute.

We provide a full range of advice on IP, including patent drafting, patent term extension (PTE), protection of research results, product life cycles, patent and trademark prosecution, portfolio management, brand and trademark clearance, labelling, advertising and marketing, Supplementary Protection Certificates, anti-counterfeiting and falsified medicines, employee inventor compensation, licensing and commercialization of results from research and trials, and data exclusivity. Our team also provides a full range of IP litigation services. We have on-the-ground global reach and understanding to help you enforce protection of your proprietary innovations in every corner of the globe.



Recent examples of our work includes advising:

- and defending at court a leading international pharmaceutical group in patent revocation, infringement, injunction and Anton pillar disputes
- and defending at court a leading international pharmaceutical group in patent infringement proceedings including damages compensation controversies
- a German multinational pharmaceutical company in several patent litigation actions in Russia against a Russian generic manufacturer
- an Italian pharmaceutical company on a potential patent dispute
- a pharmaceutical corporation on potential disputes on parallel import of medical devices
- an international pharmaceutical company on the proposed purchase of a manufacturer of biological active additives and conducted the complex due diligence of the IP assets of the target company and advised the client on possible risks
- and patenting antiviral nucleosides for therapeutic administration
- and patenting novel vaccine compositions for major US research institutions
- and patenting COVID-19 diagnostic platforms and devices for blood collection and separation
- and developing a patent and trademark portfolio for a French company in the area of transcutaneous immunization compositions, methods and devices
- a patent prosecution for a European biotechnology company in the area of red blood cells as a therapeutic delivery mechanism
- a patenting antiviral nucleotides for therapeutic administration
- a leading personalized medicine company developing lipid biomarker technology on all of its patent matters

Manufacturing and logistics contracts

With demand far outstripping supply for COVID-19 vaccines, many national governments have entered into Advance Purchasing Agreements for vaccine production which allowed pharmaceutical companies to invest in production while vaccines were still at the clinical trials stage.

Any manufacturer faces critical risk areas in relation to the availability of raw materials, the capacity of manufacturing production and the quality assurance process, all of which need to be addressed in the terms of manufacturing contracts.

Eversheds Sutherland's Global Strategic Contracting Team has the expertise to support manufacturers and purchasers of vaccines with the drafting and negotiation of manufacturing contracts. Our Team can also support with related contracts for the transportation and storage of vaccines.



Recent examples of our work include advising:

- Cell and Gene Therapy Catapult on a UK government investment of more than GBP 100m to produce millions of doses of a COVID-19 vaccine, enabling these to be made available as soon as possible
- a Finnish pharmaceutical company on a commercial relationship with a partner in relation to contract manufacturing and distributorship of BAA (food supplements)
- a global pharmaceutical company on establishing drug packaging and distribution arrangements with a local Russian contractor
- a leading Russian producer of medical diagnostic equipment on entering into agreements with a multinational technology company to open a new production facility for high-tech medical equipment in Russia
- adapting logistics agreements for the transportation of healthcare products for use in 8 different jurisdictions
- a NASDAQ-listed German-based global biopharmaceutical company in a manufacturing JV for a COVID-19 vaccine for the Greater China market with a major pharmaceutical manufacturer listed in Shanghai and Hong Kong





Product liability

The development and licensing for authorized use of vaccines against COVID-19 in a 12 month period is an incredible achievement given that it often takes a decade to develop a successful vaccine against new disease. In many countries, the availability of vaccines has been possible only due to emergency authorizations.

Vaccine producers and suppliers face the prospect of civil liability and, in some jurisdictions, criminal liability for a variety of different reasons ranging from manufacturing defects to failures to provide adequate warnings. Some countries have adopted a position that the procuring authority will accept defect liability and indemnify the producer to facilitate the smooth roll-out of vaccination in response to the COVID-19 pandemic. Given the urgency and rapid pace of the roll-out, producers and procuring authorities should be alive to the possibility that corrective actions may be required in the field where safety issues subsequently arise.

Eversheds Sutherland's international team of lawyers with product liability experience can provide strategic advice on preparation for and response to product issues. Our team can help you make the right decisions as to appropriate remedial actions, and handle the often complex and technically demanding claims and prosecutions arising from product failure.



Recent examples of our work includes advising:

- and defending at court one of the leading international manufacturers in vaccines product liability litigation related to thimerosal, mercury and child autism disorders
- and defending a leading international vaccine manufacturer in criminal investigation related to the purported defectiveness of the varicella vaccine
- a global life sciences business in relation to management of claims arising across multiple jurisdictions following the recall of a serum
- defending a leading pharmaceutical company on claims for side effects arising out of historical prescriptions
- on the contractual provisions regarding product liability in contracts for the supply of syringes for COVID-19 vaccines
- on the protocol and indemnity arrangements for clinical trials and the withdrawal of participants from such trials
- on the recall of a therapeutic medicine in Australia and New Zealand, including liaising with regulators and management of customer claims
- a leading US-based biopharma company on the development of an EMEA-wide product incident plan to include pharmacovigilance and regulatory notifications

Regulatory

Our Global Regulatory Team advises some of the largest multinational companies in the pharmaceutical sector.

Our Global Regulatory Team can advise you on negotiating procedures with government bodies which may involve purchases made through public tenders; on centralized purchase procedures organized by national governments; and on procurement via framework agreements with other regional authorities.

Our work includes advising on government contracts at national and regional level including with health authorities and hospitals relating to vaccines and vaccination, market authorizations and pharmacovigilance. In some jurisdictions we also represent our clients in important legal disputes at administrative courts and judicial review courts (including supreme courts), for example regarding the award of vaccine procurement contracts and the selection of the most suitable vaccines.

We can advise you on the registration and market authorization of approved drugs in many countries around the world, including vaccines, as well as on collaborations with other companies or research organizations regarding market access or marketing authorization related matters. We can also advise on the interaction of existing marketing authorization(s) in various territories around the world and obtaining marketing authorizations in other territories. We provide support on how to approach such processes and resolve potential issues that may emerge in respect of obtaining a marketing authorization.



Recent examples of our work include advising:

- a large multinational pharmaceutical company in Spain in a dispute at Judicial Review Courts (including Supreme Court) against various Regional Health Authorities related to the purchase of vaccines for children included in the National Vaccines Program of the Spanish Government
- various multinational pharmaceutical companies in relation to the local distribution, financing and pricing of COVID-19 medicines to COVID-19 purchased by emergency EU procedures or by pan-European purchasing legal mechanisms
- a large multinational pharmaceutical company about the administrative procedure for the inclusion of vaccines in the list of financed medicinal products by the UK's National Health Service (NHS) and the determination and negotiation of the NHS price. We dealt with the serious problems arising with the interactions between this Pricing and Reimbursement local procedures and the purchase contracts at EU level
- a US based pharmaceutical company in relation to launching a new biological medicine in Russia, exploring potential market authorization and exclusivity parameters
- a Finnish pharmaceutical company on a quality and safety agreement with a commercial partner, establishing the areas of responsibility and streamlining the obligations related to pharmacovigilance
- on a regulatory audit of a major manufacturer of generic medicines; reviewing internal documents and procedures concerning product safety, relationship with HCPs and regulators



Awards



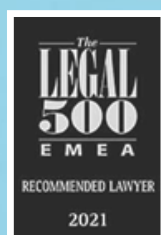
Nominated for **Life Sciences Team of the Year** for the British Legal Awards 2020



Cedric Lam recommended under Enforcement and Litigation; Prosecution and Strategy; and Transactions



Consistently ranked in **Chambers & Partners, Legal 500** and **Iberian Lawyer** for Health and Life Sciences



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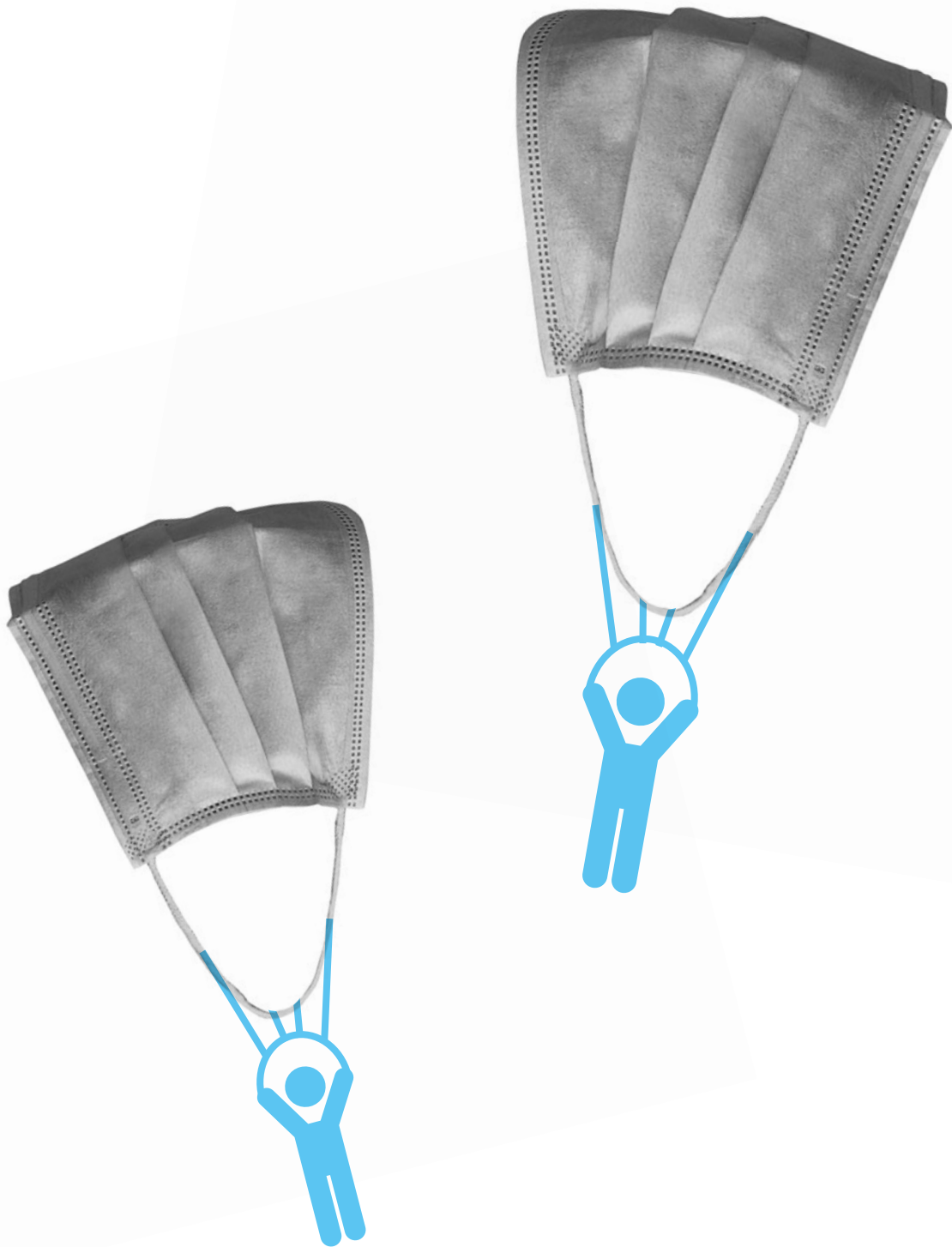
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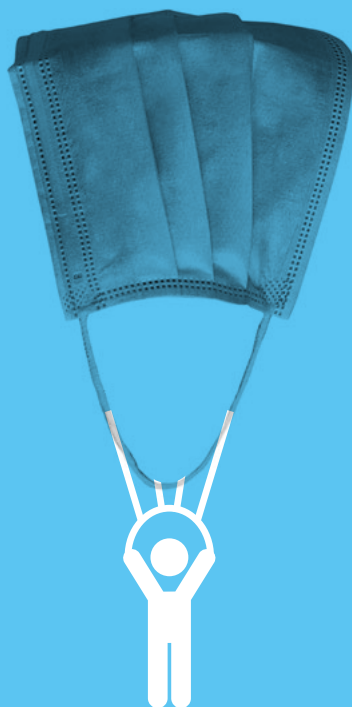


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