

A vital sector Life Sciences & Healthcare

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With big deals fuelling record levels of M&A activity, a steady stream of innovative and disruptive technologies, new and increasingly complex regulatory challenges and a thriving start-up community, life sciences and healthcare is one of today's most dynamic global sectors.

Transaction levels look set to stay high. But, as larger companies look for new ways to create value and extend their offerings in line with environmental and social demands, major transactions are giving way to smaller, bolt-on deals.

New and emerging product areas attracting investment include cannabis, with a rising number of registered IP rights highlighting strong competition to establish and build markets. Retirement-related products and services offer a host of business opportunities. Changing lifestyles and consumer preferences are focusing biotech on developing alternative meat products.

A thriving start-up community now plays a key role, contributing new ideas, products and services across the sector – including leading-edge Al applications for new drug development.

Technology is driving ongoing innovation and disruption in many areas, including gene therapies and intelligent drug discovery and development. Products and services are evolving as demand builds for consumer wearables, telemedicine and an extended range of health apps.

While these developments enhance patient care and well-being, they also raise questions about digital data collection and ownership. Can companies maintain consumer trust?

Patent protection remains a key issue for product development and commercialisation. Shorter patent times and an increasing range of generics are key factors.

The sector faces complex regulatory challenges. Regulation needs to keep pace with scientific advances – including technological changes in pharma and medical devices and the commercialisation of gene and cell therapies – as well as the economic, social and political factors.

If you would like to discuss these or any other developments, please get in touch. We would be delighted to talk about your interests and concerns.



Global solutions

In a highly regulated global sector that is constantly evolving, you need lawyers who truly understand your local and cross-border goals. CMS sector specialists deliver local legal and industry expertise with a global outlook, where and when you need us. Our global life sciences and healthcare team offers you proactive support across Europe, Africa, the Middle East, South America and Asia-Pacific.



Full service plus

We are one of the few law firms who can advise you across the full spectrum of legal, regulatory and commercial issues affecting your business. Our services cover complex regulatory, product liability, competition, procurement, commercial and IP issues – including patent prosecution, EPO opposition and regulatory exclusivity product life extension. We can also advise on your disputes, M&A and financing.

Our team includes lawyers, scientists, patent attorneys and academics, and a number of our team have worked in-house. With such a complete team, we pay just as much attention to industry trends and the bigger picture, and what they mean for our clients as to the issues of today.



Committed to your future

It is only possible to be prepare for the future when you truly understand the present. A key point of difference for CMS is its depth of understanding, and hence leadership, in the life science and healthcare sector. This deep knowledge creates the ability to anticipate further challenges, innovate and move quickly to meet them.

CMS helps you keep on top of key legal and regulatory issues. Many of our lawyers are active members of leading industry bodies,

including the Association of the British Healthcare Industries (ABHI), Association of the British Pharmaceutical Industry (ABPI), MedTech Europe, AdvaMed, Young Excellence in Healthcare (YEH) and EUCOMED. We bring you the latest news and insights into the developments impacting your industry and business, helping you to shape effective strategies and policies.



Case studies

Delivering cross-border sectoral expertise for high-value M&A deals

CMS advised Advent International on its EUR 1.9bn acquisition of Zentiva from Sanofi Pasteur. The deal was awarded Mergermarket's "CEE M&A Legal Adviser of the Year 2018" and "CEE Deal of the Year 2018" by CEE Legal Matters.

The acquisition involved multiple locations across the CEE region, including the Czech Republic, Hungary, Romania, Poland and Slovakia, as well as Switzerland. CMS provided a dedicated team of over 50 lawyers, coordinated from the UK and Bulgaria, to deliver pharmaceutical sector and cross-border expertise. Our advice covered all key aspects of the deal, from due diligence to finance, including the various local restructurings required to effect the pre-completion carve-out.

Advent followed its purchase of Zentiva with the bolt-on acquisition of the CEE business of Alvogen, a global generic and OTC pharmaceuticals manufacturer. CMS again provided full cross-border support for the deal, which was one of the highest value M&A deals in CEE in 2019 and was awarded CEE Deal of the Year 2019 by CEE Legal Matters.

We have also once again been awarded for our work with Advent and Zentiva at the CEE Legal Matters Deal of the Year 2019 Awards where we won Czech Republic Deal of the Year 2019.



CEE M&A LEGAL ADVISER OF THE YEAR

Chambers & Partners



This firm bristles with the talent and experience necessary for a comprehensive life sciences practice, and excels accordingly. Core areas of strength include product liability and patent litigation, competition law, regulatory advice, commercial and corporate support.

Mapping the legal landscape for a medicinal cannabis start-up

CMS provided advice and guidance to a pioneering start-up on the legal framework for selling medicinal cannabis, produced in California, in multiple European countries. Our advice covered the cultivation, import, sale, supply and marketing of medicinal cannabis in EU jurisdictions including the Netherlands, Italy, UK, Belgium, France, Germany, Portugal and Spain.

CMS is a leading adviser to the medicinal cannabis industry, which has become a growth business in recent years. Our advice reflected the evolving political and ethical implications of the cannabis business and the different regulatory approaches being taken within the EU.

Legal 500



'A global powerhouse with deep expertise in the healthcare and life sciences sector', CMS earns a top position thanks to its genuine dedication to the field. Delivering 'strong knowledge of the applicable law', 'significant practical experience' and a 'consistently thorough approach'.



The numbers

Healthcare and life sciences: Switzerland, UK (London and Scotland) Legal 500



Life Sciences and Healthcare: **Hungary, Scotland**



Chambers & Partners











world's largest biotechnology company



start-ups



(A) Healthcare Law Firm of the Year

JuVe Germany 2019





Legal Advisor - Independent

> LaingBuisson Health & Social Care Awards 2019, 2021 UK



CEE Legal Matters 2019

480+ lawyers, patent attorneys, scientists and academics globally

FOUNDED LIFESCIENCES ASIA-PACIFIC NETWORK WITH MEMBERS IN NINE JURISDICTIONS

Our track record



Growing healthcare businesses

ST Pharm Co. Ltd.

On the acquisition of a 70% stake in AnaPath Services, a Swiss contract laboratory services and histopathology company whilst simultaneously advising AnaPath Services on its 100% acquisition of Spanish contract research organisation, Envigo CRS involving the coordination of three jurisdictions.

Welltower, Inc.

On the USD 4.3bn acquisition of Sunrise Senior Living – Welltower's entry into the UK market. We subsequently advised on the acquisitions of over USD 500m of care home assets and the GBP 226m sale and leaseback of four acute care hospitals.

Realm Therapeutics

On the placement of new shares and warrants valued at GBP 19.3m in the UK and the US with new and existing investors, including several specialist healthcare funds.



Johnson & Johnson

On a successful infringement litigation case regarding imitations of medical devices across multiple jurisdictions, including Austria, the Netherlands, Slovenia, Germany, Belgium, Croatia, Italy and France.

A global US manufacturer

On defence against a threatened group litigation order by almost 30 claimants following a medical device alert concerning implantable devices.

A major international life sciences company

On multinational product liability coordination involving crop protection products across six jurisdictions.



A global medical devices company

On a comprehensive strategy and related agreements – covering commercial, regulatory, tax, transfer pricing, forex and IP issues – for licensing IP to Chinese subsidiaries that manufacture devices for local and global markets.

GW Pharmaceuticals

On regulatory advice to the UK biopharmaceutical company on the marketing of drugs containing psychotropic substances, covering issues including warehouse authorisations, reimbursement procedures and access to special marketing programmes for innovative drugs.

Echo

On the sale of Echo, a UK start-up whose app helps people manage their medication and order repeat prescriptions for delivery, to leading healthcare organisation McKesson, owner of LloydsPharmacy.



Patents and regulatory exclusivity

Eli Lilly

On representation before the European patent office in contested proceedings relating to CGPR monoclonal antibodies in pain treatments.

An Australian medical device company

On anti-bribery and regulatory risks advice across multiple jurisdictions in Europe and Asia.

Boehringer Ingelheim

On healthcare advertising, competition law and regulatory advice covering several substantial matters.

Smart service delivery

The Life Sciences and Healthcare sector pushes boundaries, and so do we. Our clients benefit from bespoke CMS-developed tech as well as industry-standard AI. Here are just a few examples of how we use technology to deliver for clients.

Al delivering savings

Disputes often involve large volumes of documentation, and that's particularly true in a heavily regulated and IP-intensive sector such as life sciences and healthcare. Our CMS e-disclosure team, CMS Evidence, provides the latest e-disclosure tools to review, analyse and organise documents in a cost-effective way. It means that we can scope, budget and manage the entire disclosure process from start to finish, saving time and money. Due diligence, data and contract analysis can be time-consuming and complex. We use AI tools to review large swathes of information quickly and cost-effectively. The software enables us to cluster, compare, analyse and visualise data from multiple sources and search thousands of documents accurately.

Responding to investigations

So called dawn raids – unannounced inspections – are an established and increasingly frequent feature of the regulatory landscape. The CMS Dawn Raid app gives our clients instant, 24/7 access to CMS experts whenever the authorities come knocking. Developed in cooperation with our global competition practice, the app includes jurisdiction-specific checklists and best practice guidelines. Download it from your app store.

Mobilising after data breach

Companies are rightly devoting more and more resources to cybersecurity, but most will still suffer a breach sometime. With brand reputation and customer trust at risk, as well as intellectual property and data privacy, the cost of data breaches and increasingly sophisticated cyberattacks is increasing.

A rapid response in the aftermath of a breach is critical.

CMS can help. Our Breach Assistant app helps you to understand the priority actions you should take when faced with a breach and you can contact CMS data breach response lawyers at the touch of a button.

Download the app from <u>breachassistant.com</u>

Chambers & Partners



Solid across the full cycle of life sciences matters, with respected teams in Asia and a spread of offices across Europe. Well versed in regulatory, transactional, product liability and IP work.



Sharing with you

We keep a close eye on developments and trends in this ever-changing sector to offer you insights, commentary and perspectives across multiple channels.

AI in Life Sciences



Examining the impact of AI and it's use in the life sciences industry, the guide covers the increasingly important Chinese legal landscape and reviewing "ethical AI" – including what AI developers can do to ensure that their products are trusted by consumers. Download the report at cms.law

Digital health apps and telemedicine



Digitisation is advancing steadily. Its pioneering innovations challenge all parties involved. Is the software a medical device? Who should be liable if the digital health app is wrong? How is the sensitive health data protected? What is the legal framework for telemedicine – the demand for which has grown significantly in the last year? This Expert Guide provides high level information on digital health apps and telemedicine in more than 20 jurisdictions. It offers comparison of the applicable laws, issues, regulatory aspects of the classification of digital health apps, data protection laws, as well as the legal framework for telemedicine. Visit https://cms.law/en/int/expert-guides/ cms-expert-guide-to-digital-health-apps-andtelemedicine_

A legal roadmap for Cannabis



The cannabis trade and related activity is a growth business. A growing number of patients now have access to medicinal cannabis, and its potential therapeutic value is gaining wider acceptance. Our guide provides high level information about the legal approach to regulating cannabis across multiple jurisdictions. Visit https://cms.law/en/int/expert-guides/cms-expert-guide-to-a-legal-roadmap-to-cannabis

Global Life Sciences & Healthcare Festival



Our annual festival attracts more than 100 guests, as they join industry experts and CMS lawyers to learn more on the key issues bringing innovation and disruption to their sector. To learn more about this year's festival, please get in touch with our Global Co-Heads or your key CMS contact.

Advertising of Medicines and Medical Devices



The Expert Guide provides high level information on life sciences and healthcare advertising across multiple jurisdictions and offers a quick and simple understanding of the applicable laws. The Expert Guide covers, amongst others, different types of advertising, regulatory aspects as well as legal consequences of non-compliance. Visit https://cms.law/en/int/expert-guides/cms-expert-guide-to-advertising-of-medicines-and-medical-devices

On the Pulse series



On the Pulse brings together CMS lawyers and experts to discuss key industry topics impacting, innovating and disrupting the life sciences & healthcare sector. Download the series at https://cms.law/en/int/publication/on-the-pulse

Keep in touch





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Law-Now



You can subscribe to receive our updates and commentary on sector-specific news by email. Law-Now – our award-winning, customisable legal and business news portal – includes dedicated Life Sciences and Healthcare sections. Register at cms-lawnow.com.

CMS

Staff

Lawyers Partners

> 8,000 > 5,000 > 1,100

52 new partners in 2021, taking the total to over 1,100

Operating in

Across

EUR 1.475bn

turnover for 2020

19 Practice and Sector Groups working across offices

Top rankings in M&A league tables by deal count

- #1 Germany, DACH, Austria
- #2 Europe, UK, Switzerland, **Benelux**





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CMS locations

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