

CMS CEE

Anti-counterfeiting and Illicit Trade

In the pharmaceutical and medical devices sector

Introduction

Despite COVID-19 vaccines being only a few months old, we are already seeing the confiscation of counterfeit vaccines and the illicit trade of genuine vaccines. For those in the life sciences and health care sector this is no surprise - counterfeiting medication is an extremely profitable business, with sales estimated at EUR150 - 200 billion annually, and counterfeit pharmaceuticals are the most lucrative sector among traded fake goods.

With significant margins between the cost of manufacturing fake products and their sale price and the low risk of getting caught and prosecuted, it is an appealing business, and an as lucrative practice, where no manufacturing is even involved is the illicit trade of medical products, explicitly the theft or diversion of genuine products. These are approved and intended for sale in a particular country, region or city, but are intercepted and illegally diverted to a different geographical area or group of recipients, others than those intended.

Both counterfeiting and illicit trade can have fatal consequences. According to a 2020 report by the OECD and EUIPO, estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs. With illicit trade, although there is limited data, the diversion of products means the individuals they were intended for are denied or delayed their required treatments, while those getting access to them take on the risks of administering products supplied and stored outside of the legitimate supply chain, with no guarantees of compliance with the GxP. Finally, the states and communities are missing billions in unpaid taxes.

Both practices also pose major risks for those companies active in life sciences and health sector; irrevocable damage to brand, market and reputation, risk of recall and liability suits and non-compliance. Because they operate globally, tracking and detecting the sources of counterfeit or stolen products is difficult, and data providing a clear overview of the scale and set-up of these illegal industries is still sparse.

However, many countries, international organisations and supranational unions, including the EU, are starting to address this through collaboration and we are seeing the implementation of more proactive and rigorous anti-counterfeiting and illicit trade measures. For these to come into fruition and to be successful, advocacy and support from those active in the life sciences and health sector is needed to push this forward.

CMS can help you in battling illicit trade and counterfeiting - we can work with regulators and authorities to ensure the necessary legislation is in place to deter those involved in these illegal operations. We also support on the full life-cycle; from IP and brand protection, securing your supply chain, data collection and compliance, to investigations, criminal proceedings and cooperating with local and/or international bodies.

We regularly support international clients in devising comprehensive, company-wide strategies to protect their products and supply chain and crack down on those illegally seizing, commercialising and counterfeiting their products.

We do hope this brochure is of interest to you and please feel free to get in touch with us or your local CMS advisor



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Strong on the areas that matter to you

Achieving business success in highly regulated markets requires effective management of commercial risks and of your supplier and customer relationships. As an international or global business, you can rely on our advice on complex and multi-jurisdictional issues, including trade and customs, and our knowledge of the regulatory and commercial issues facing your sector. We have advised many internationals operating in the CEE region over the years and continue to assist them as they secure, protect and grow their operations and networks.

Our advice is informed by an in-depth understanding of the life sciences and healthcare sector and covers all critical opportunities and challenges for your business, including globalisation, online marketplaces, supply chain management, increasing consumer pressure and media scrutiny.

Among others, we advise on regulatory, criminal and civil proceedings, intellectual property and shaping with legislation and working with authorities:

Regulatory

- Marketing authorisation
- Use of non-authorised products
- Quality control
- Pharmacovigilance
- Conformity assessment
- Market surveillance

Criminal & Civil Proceedings

- Tracing & monitoring
- Anti-counterfeiting criminal prosecutions
- Civil enforcement
- Internal & external investigations
- White collar crime
- Compliance issues

Intellectual Property

- IP registration
- Portfolio management & strategy
- IP enforcement
- Brand management & protection
- Advertising, sponsorship and marketing
- Commercial agreements
- Licensing, technology transfers research, development and exploitation agreements outsourcing
- Transactional IP
- Anti-counterfeiting online
- Trade secrets

Shaping Legislation & Working with Authorities

- Engaging with and assisting enforcement agencies
- Trade and customs authorities
- Sharing of data and information
- Product safety and recalls
- Actively working with governments to change or enforce legislation
- Negotiating with national and EU regulators
- Lobbying & advocacy
- EU white papers
- Precedent setting cases

Working with CMS

We believe that working with CMS in the CEE region can offer you numerous advantages, as we provide:



Sector specialists – our group of pan-CEE life sciences lawyers work alongside scientists, academics, regulatory, anti-corruption and IP experts, all of whom have a deep understanding of your legal and regulatory needs to provide you with practical, commercial and sector specific solutions. In addition, many of our team have worked as in-house lawyers for life sciences companies, enhancing our knowledge of your business.



Trusted advisers with an extensive track record – you want to work with lawyers who have the experience and sector specialism of supporting clients in the medical devices sector. Our group works with the top 100 Life Sciences companies, including the top 20 global pharma companies and the top 10 global medical device companies, which shows we are trusted by your peers to support them and you on your strategically important projects and investments.



Full service sector offering – we are one of only a few firms offering the strength and depth of expertise across all the key areas of interest to your sector – so whilst we advise on complex regulatory, advertising, product liability, competition, procurement, IP, IT, data protection, cyber security, transactional and commercial issues, we are also able to deal with the more exceptional disputes, investigations and criminal matters.



We are the no 1. International law firm in the CEE – we have exceptional coverage across CEE, and with more than 30 years of experience in the region, we have a full understanding of the local markets. Furthermore, with our geographical footprint and more than 500 lawyers, CMS is also the largest law firm in the region. This distinguishes us from the rest of the market and allows you to access specialist services in every jurisdiction where you need it.



One central point of contact – we have deep experience of providing seamless multi-jurisdictional advice for clients with a regional or international presence. We provide one key relationship partner who will ensure work is delivered to schedule, commercial aims are met, and all queries are promptly answered.



Clear commercial advice - we ensure that our advice, documents and materials are consistent; our key aim is to ensure that we provide clear and commercial advice. We won't write long academic essays. Instead we focus on providing advice which can easily be shared with and understood by your co-workers and other business professionals.



Value for money - as experienced advisers to companies such as yours, we know that value for money is a key. Our fees are competitive with fees offered by other international law firms in the CEE. We are generally happy to offer fixed or capped fees to provide certainty. We are also able to offer innovative fee structures including success fees and satisfaction-based fees.



Strong industry reputation – you will be working with a highly distinguished sector group recognised by the legal directories, including Chambers Global, the local Chambers & Partners guides, Legal 500, LMG Life Sciences Europe and Who's Who Legal: Life Sciences. We have also been the number one law firm for the number of completed M&A deals in the Life Sciences sector in Europe by Mergermarket.

Detailed case study

Seven global top-20 pharmaceutical companies in a large scale investigation beginning in 2019 and currently on-going.

Our Ukraine Life Sciences & Healthcare team advises a group of global leading pharmaceutical clients on all key aspects of and represents them as criminal complainants in the most significant criminal investigation of counterfeit medicines in Ukraine to date. In the course of the investigation more than 160 illegally commercialised medicines have been seized, including 24 (mainly expensive oncological medicines, as well as antiviral products and orphan medicines) suspected to be counterfeit. The suspected illicit trade and counterfeiting activities affected 18 markets, including the US and several EU countries.

As this is the first large scale investigation of counterfeit medicine in Ukraine, assisting is complex as it:

- involves navigating the imperfect Ukrainian legislative landscape;
- requires dealing with the general unfamiliarity of both the law enforcement authorities and courts with the legal and practical aspects of the case; and
- involves the specifics of sector regulations and IP protection in the pharmaceutical industry and illicit drugs trade.

Our assistance includes:

- advising on various IP, regulatory and criminal procedural matters in terms of the investigation;
- cooperation with our clients' security, commercial, quality assurance, legal and IP teams;
- handling all procedural aspects of our clients' involvement in the criminal proceeding;
- identifying and documenting violations of the clients' IP rights;
- regular communication with the investigators, prosecutors, analysing the case materials and identifying potential violation of our clients' IP rights;
- obtaining samples of the seized products and components for the purpose of internal laboratory testing by our clients, as well as collecting genuine samples of medicines from our clients and providing the law enforcement agencies with such samples for the purpose of public lab testing;
- close monitoring of the developments in the case and updating the clients, advising them on the necessary or recommended actions in light of such developments, finding ways to obtain additional evidence of violation of our clients' IP rights by the suspects and advance the investigation; and
- representing our clients as criminal complainants before the law enforcement agencies and courts during the investigation and trial proceedings.

Other recent relevant experience

Roche

On legal advice relating to the implementation in Ukraine of the Anti-Counterfeiting and Grey Import Campaign, including defining the gaps in the regulatory, criminal and criminal procedural legislation, as well as providing recommendations on domestic legislation development and alignment with the European standards and the Council of Europe Medicrime Convention provisions.

Three global top-20 pharmaceutical companies

On one of the largest on-going criminal investigation of counterfeit medicine in Ukraine. Our assistance includes monitoring the developments in and advising on the on-going criminal proceeding regarding counterfeiting and illicit trade in medicines, identifying and documenting violations of our clients' IP rights, regular communication with the investigators and prosecutors, analysing the case materials and identifying potential violation of our clients' IP rights, and cooperation with our clients' security, IP, legal and commercial teams.

Eli Lilly and Company

On trademark, design and unfair competition matters since 2005. Particularly, we have been in charge of brand enforcement activities for one of the most counterfeited pharmaceutical products in the world, Cialis®, with several thousand cases and several high-profile litigation matters over the years, including criminal cases pursuing networks of counterfeiters bringing ancillary trademark claims in court and helping achieve both significant sentences and damage compensation. In addition, we are also regularly advising on Lilly's trademark and design protection strategy.

Novartis

On regulatory data and patent protection against generics entry in the Czech Republic.

A global medical devices company

On several criminal investigations on alleged bribery, corruption and compliance issues.

A multinational pharmaceutical company

On an investigation, including cooperating with national authorities, into counterfeit and illicit trade and distribution and/or diversion of COVID-19 vaccinations.

A pharmaceutical company

On distribution models (DTP), parallel trade issues as well as public procurement in the Czech Republic.

ITP – Biomedical Company

On a case concerning multinational opposition proceedings against its key international trademark in twelve jurisdictions including United Kingdom, Turkey, Switzerland, USA and Mexico.

A global top-20 pharmaceutical company

On Ukrainian legal issues related to suspicious products originating from Ukraine and identified by the company as counterfeit.

A global medical technology company

On several criminal investigations into alleged bribery, corruption and compliance issues in the Czech Republic.

A major Swiss chemical and biotechnology company

On various patent and SPC related issues, including parallel import and national or EU customs applications.

Roche

On an unfair competition, libel and slander dispute with the distributor of a competitor's medical devices.

Prosfitt Technologies

On the registration of a conflicting trademark and on a preliminary research to register a patent for a utility model regarding their prosthetic fitting software.

A global pharmaceutical company

On anti-counterfeiting advice. We assisted this world leading pharmaceutical company with running its customs IP protection programme in Poland. This is aimed principally at counteracting the import of fake medicines.

A German pharmaceutical company

On patent issues associated with anti-counterfeiting encryption technology used on the packaging of their pharmaceutical products.

Syngenta

On all anti-counterfeiting cases in Poland, including actions against distributors and importers of counterfeit products. Our role was to work closely with the customs and police, launch and conduct criminal proceedings. We also assisted Syngenta in civil cases against major importer of whole amounts of counterfeit crop protection products and on enforcement before the Polish settlement court concerning the provision of information connected with trademark infringements.

L'Oreal

On IP enforcement and as their exclusive anti-counterfeiting advisor in Poland. We handle all customs and criminal seizures related to all L'Oreal brands (more than 25) and provide training to the enforcement authorities. The team works closely with the Polish customs, police forces, and the client's trademark team in Paris. The team also regularly assists L'Oreal with strategy advice regarding cases involving sale and production of the infringing perfumes in Poland.

A global science and engineering company

On the settlement of a case against a local distributor concerning the sale of potentially counterfeit food ingredients under their brand name and the related customer complaints. The case was extremely sensitive since it concerned a very important distributor for the business in Bulgaria.

Partner in Pet Food

On a cross-border basis in five European jurisdictions, Turkey and the UAE including significant IP advice regarding the expansion and protection of their trademark portfolio.

A leading international agrochemical company

On patent infringement, anti-counterfeiting, customs and regulatory dispute work including coordinating with other CMS offices around Europe and bringing together a network to service the client's needs.

A Swedish online retailer

On filing the complaint with the Intellectual Property Protection Platform of Taobao of a hyped Swedish fashion company and a Chinese entity who established a fake website on the Taobao platform which pretended to be the client's Chinese website.

Bayer AG

On a project aimed at investigating an organised crime group smuggling counterfeit crop protection products into Poland.

A health & beauty company

On suspected cases of the sale of counterfeit products of their health and beauty supplement for hair.

A major international consumer products company

On developing a global anti-counterfeiting strategy.

A leading global manufacturer of electronic instruments and electromechanical devices

On the possible legal actions against counterfeiting in China.

A world-leading supplier of edible coatings to the pharmaceuticals industry

On a patent infringement matter spanning a number of jurisdictions, including China.

A crop protection corporation

On patent and trademark litigation and product piracy.





Where you need us







<p>CMS ALBANIA Based in Tirana Established 2012 > 7 lawyers</p>	<p>CMS BOSNIA AND HERZEGOVINA Based in Sarajevo Established 2008 > 10 lawyers</p>	<p>CMS BULGARIA Based in Sofia Established 2005 > 40 lawyers</p>	<p>CMS CROATIA Based in Zagreb Established 2003 > 25 lawyers</p>
<p>CMS CZECH REPUBLIC Based in Prague Established 1991 > 40 lawyers</p>	<p>CMS HUNGARY Based in Budapest Established 1989 > 75 lawyers</p>	<p>CMS MACEDONIA Based in Skopje Established 2017 > 4 lawyers</p>	<p>CMS MONTENEGRO Based in Podgorica Established 2012 > 4 lawyers</p>
<p>CMS POLAND Warsaw and Poznan Established 1990 > 170 lawyers</p>	<p>CMS ROMANIA Based in Bucharest Established 1999 > 65 lawyers</p>	<p>CMS RUSSIA Based in Moscow Established 1992 > 50 lawyers</p>	<p>CMS SERBIA Based in Belgrade Established 2000 > 18 lawyers</p>
<p>CMS SLOVAKIA Based in Bratislava Established 2017 > 10 lawyers</p>	<p>CMS SLOVENIA Based in Ljubljana Established 2008 > 15 lawyers</p>	<p>CMS TURKEY Based in Istanbul Established 2013 > 20 lawyers</p>	<p>CMS UKRAINE Based in Kyiv Established 2007 > 30 lawyers</p>



Your core team in the CEE

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Going the extra mile

We are committed to providing an exceptionally high level of service beyond that provided by most law firms. Our ethos is to work collaboratively with our clients to offer added-value services which help you deliver the innovation and efficiency that keeps you ahead of your commercial peers. We will work with both your legal team and senior management to ensure you receive the added value you require.

<p>Global Life Sciences & Healthcare Forum – Hosted at one of our European locations, our annual forum attracts more than 100 guests, as they join industry experts and CMS lawyers for a full day to learn more on the key issues bringing innovation and disruption to their sector.</p>	
<p>Vaccine Compensation Regimes in the CEE & Russia -provides high level information on vaccine compensation and reimbursement regimes in eight jurisdictions in the CEE region and Russia and offers a quick and simple understanding of the applicable laws, on what is a complex yet incredibly important topic as we move towards the vaccination of populations to stop this global pandemic. View here...</p>	
<p>Advertising of Medicines and Medical Devices – This 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. Download here...</p>	
<p>AI in Life Sciences – Examining the impact of AI and its 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 here....</p>	
<p>Digital Health Apps and Telemedicine - This Guide provides high level information on Digital Health Apps and Telemedicine in more than 20 jurisdictions. It offers a quick and simple understanding and comparison of the applicable laws and covers, amongst other issues, regulatory aspects of the classification of digital health apps, data protection laws, as well as the legal framework for telemedicine. Download here...</p>	
<p>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 here....</p>	



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