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Presenting our Lifesciences & Healthcare practice

Why CMS?

Sector specialists
Strong expertise and high-quality advice delivered from dedicated lawyers working alongside sector specialists including scientists, academics, regulatory, anti-corruption and IP experts, all of whom understand the legal needs and issues of the lifesciences sector.

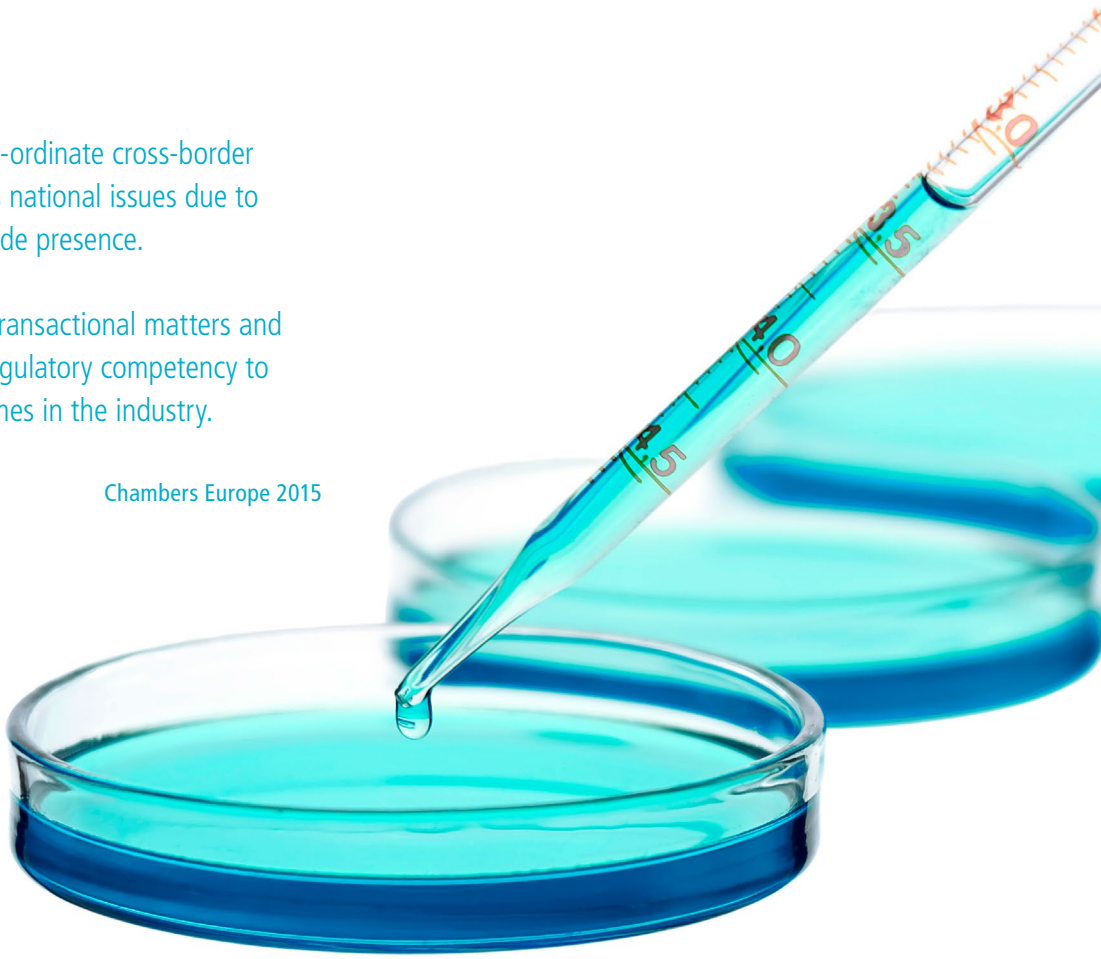
Working with the lifesciences and healthcare community
CMS Lawyers participate and are invited as speakers in forums and roundtables with key industry bodies, including Eucomed. Through these partnerships, we not only share news and developments impacting the industry and business of our clients in a timely manner, but we also take a role in shaping and drafting policies to ensure that the needs of our clients are met, as they operate in this highly regulated sector.

We regularly work for hospitals and public authorities. Our knowledge of the environment in which hospitals operate and our relationship with the public authorities allow us to provide unrivalled insights and added value to our lifesciences clients.

Trusted advisers with a strong reputation
We work with and have established long-term relationships with the top 100 lifesciences companies in the areas of pharmaceutical, medical devices, biotechnology and agriculture, including most of the top 20 global pharmaceutical companies and the top 10 global medical devices companies. This demonstrates our strength in developing deep and trusted relationships with those in the sector, as we deliver practical, technical and commercial legal solutions. We have been appointed to the European Commission expert group on public procurement and many of our lawyers are recognized by leading legal directories.

International footprint
CMS is the largest law firm in Europe, with 59 offices in 33 countries, including Algeria, Brazil, China, Mexico, Morocco, Oman, Russia and United Arab Emirates, to support you and your key growth markets. We are also developing relationships with local leading law firms in the Asia-Pacific region through the Lifesciences Asia-Pacific Network (LAN) to further support our clients and their investments in emerging markets.

> Well equipped to co-ordinate cross-border mandates as well as national issues due to extensive Europe-wide presence.
>
> Skilled at handling transactional matters and also offers IP and regulatory competency to some of the top names in the industry.
>
> Chambers Europe 2015




Regulatory
— Clinical trials regulation and contracts
— eHealth
— Biobanking
— Reimbursement
— Regulatory pharma and medical devices
IT and data protection
— IT and BPO sourcing contracts
— Cloud contracts
— Digital transformation projects
— Big data
— Data protection and information security
IP, manufacturing, supply
— R&D agreements
— Commercial manufacturing and supply agreements
— Clinical trial agreements
— CRO agreements
— IP licence agreements
— IP strategy and IP litigation
Employment & Pensions
— Exemption from social security
— Rewards and incentives
— Know-how and IP retention
Tax
— Exemption from withholding tax
— Tax treatment of royalties
— VAT
Corporate/M&A
— Joint ventures
— Start-ups and spin-offs
— Private placement
— Corporate governance
Public procurement
— Business strategy in line with public procurement rules
— Drafting and negotiating contract documents
— Challenging or defending award documents

A Proven Track Record

Relevant experience includes:

— Assisting an **international leading medical devices company** in defining its business strategy since the application of the public procurement rules to hospitals

— Assisting a **global healthcare company** in negotiating various R&D agreements and contract manufacturing agreements regarding a new preventive medicine

— Supporting **several hospitals** (including university hospitals) and purchasing bodies in the organization of their public procurement procedures

— Assisting **various hospitals** with regard to the procurement of heavy medical equipment (PET scanners, etc.), in the conception and execution of renovation and construction works and in drafting specifications and requirements for developing laboratories

— Assisting **various hospitals** in drafting procurement specifications for works contracts, including public financing aspects and assistance during the performance of the contract

— Assisting **various major Belgian hospitals** in drafting and negotiating IT outsourcing contracts

— Advising clients on various regulatory issues related to the distribution of medicines and medical devices

— Assisting **Takeda** in its EUR 9.6 billion acquisition of **Nycomed** in 13 countries (one of the most significant M&A transactions to occur in the lifesciences sector in 2011/12)

— Assisting various **pharmaceutical companies** in the analysis of procurement specifications and in drafting their tenders

— Assisting **major pharmaceutical companies** in drafting clinical trial agreements

— Assisting **several major pharmaceutical companies** in their discussions with public authorities and ethical committees

— Advising **one of the leading pharmaceutical companies** on the data protection and information security aspects of a large IT outsourcing project (involving more than 25 jurisdictions in the EMEA area)

— Assisting a **spin-off of the University of Leuven** in negotiating and concluding a strategic alliance with a **leading pharmaceutical company** to develop disease-modifying treatments for protein misfolding disorders

— Assisting a **global biopharmaceutical company,** in the drafting of a large number of agreements, including all commercial agreements and general terms and conditions

— Assisting a **major lifesciences company** in setting up and administering European border control measures with revenue and customs and dealing with seizure of counterfeits

— Advising **Synlab Holding** on the acquisition of **Laboratoire Dr. Collard**, with 41 blood testing centres in Belgium and Luxembourg

— Conception and granting of the public service concession for the printing, distribution and follow-up of treatment certificates (this IT project was granted an e-Gov-Award)

— Assisting **various pharmaceutical and medical devices companies and hospitals** in various remedies regarding award decisions for public procurement contracts

Thought Leaders

Sharing our know-how through events

— *April 2016* - **Global Privacy Summit of the International Association of Privacy Professionals**, Washington, DC, presentation on "Data privacy in the life sciences industry: managing the challenges and leveraging the opportunities" - speaker: Tom De Cordier

— *19 November 2015* - **Seminar on the new EU directive on public procurement and the impact on the pharmaceutical sector** - speakers: Virginie Dor and Bruno Fonteyn

— *22-23 September 2015* - **MedTech Europe and Eucomed conference**, Lisbon, presentation on "MEAT public procurement for medical devices" - speaker: Virginie Dor

— *March 2015* - **Workshop about the "sunshine" of the EFPIA Disclosure Code and the data privacy aspects relating to it**, Brussels, - speaker: Tom De Cordier

— *October 2014* - **MedTech Forum 2014** - panelist and speaker: Virginie Dor

Some of our publications

— **V. DOR**, public procurement chapter in "Traité de droit pharmaceutique – la commercialisation des medicaments à usage humain", Kluwer, 2015, 131 p.

— **B. FONTEYN** and P. SLEGERS, "Personalized medicine: a major challenge for social security systems", in SCRIP Regulatory Affairs, CUBITT Consulting, 18 June 2014

— **B. FONTEYN** and P. SLEGERS, "Distribution & Marketing of Drugs, Jurisdictional Comparisons", European Lawyer Reference, 2013, p. 29

— **B. FONTEYN** and C. DUBOIS, "La plate-forme eHealth – Enjeux de santé publique et de sécurité sociale", Journal des Tribunaux, 24 November 2012, n° 6498, p. 769-776

— **B. FONTEYN**, comments about "Ziekenhuizen, mededingingsrecht en recht op kwaliteitsvolle zorg" (D. Fornaciari, S. Callens et E. Schokkaert), J.T., 2010, p. 707

— **B. FONTEYN** and P. SLEGERS, "L'utilisation de matériel corporel humain à des fins scientifiques: commentaires à propos de la loi du 19 décembre 2008", Journal des Tribunaux, 2009, p. 205

— **B. FONTEYN**, M. DENEYER and E. DE GROOT, "Het Elektronisch Medisch Dossier: uit wettelijk en deontologisch standpunt bekeken", De Praktijkjurist XV, Story, Conferentie van de Jonge Balie te Brugge, 2009, p. 1

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— Seminars and training from across CMS

Your Legal Experts in the Lifesciences & Healthcare sector

Bruno Fonteyn
Senior Associate - Lifesciences, Regulatory
E bruno.fonteyn@cms-db.com
T +32 743 69 86
https://be.linkedin.com/in/brunofonteyn

Before joining CMS' Public Law department in October 2008, Bruno worked for five years as legal counsel for the National Council of the Order of Physicians. He specializes in health law, including regulatory matters, hospitals, medical equipment, medical experiments, biobanks and other lifescience matters. Furthermore, he acts in the areas of constitutional and administrative law. Bruno is a member of the ethical committee of a university hospital, where he delivers legal opinions on medical experiments and ethical matters.

Virginie Dor
Partner - Public Procurement in Lifesciences
E virginie.dor@cms-db.com
T +32 2 743 69 72
https://be.linkedin.com/pub/virginie-dor/1/b78/597

As a specialist in public procurement law, Virginie assists public authorities and private companies in shaping public procurement procedures and competitive tenders. She also advises contracting authorities or contractors during the award process and the performance of public contracts. Her experience encompasses all economic sectors, with a particular focus on healthcare and lifesciences. Virginie is regularly invited as a speaker at conferences and gives training on public procurement regulations. She has written extensively on the subject and is the co-author of the "Pharmaceutical Law Treaty". Virginie has recently been appointed as expert for the European Commission in public procurement. She will be part of a group of 20 experts, tasked with providing the EU Commission with legal, economic, technical and/or practical insight and expertise, to help it shape the public procurement policy of the Union. As a member of this group, she will assist the EU Commission in the preparation of legislation or policy definition in public procurement. Virginie also sits on the ESIMAP board of directors, a specialist training body for public procurement.

Tom De Cordier
Partner - IP, TMC, Data Protection, Lifesciences
E tom.decordier@cms-db.com
T +32 2 743 69 13
https://be.linkedin.com/in/tomdecordier

Tom regularly assists healthcare and lifesciences clients in advisory, transactional and litigation matters relating to IP, TMC and data protection. He has extensive experience in:

— Lifesciences commercial work (e.g. drafting and negotiating research and option agreements, clinical trial agreements and strategic partnership agreements for the development of new pharmaceutical products)
— IP transactional work (e.g. drafting and negotiating cross-border patent & know-how licence agreements, complex R&D agreements, IP assignment agreements, IP reps & warranties, etc.)
— Data protection (e.g. advising on cross-border data protection compliance projects, transfers of personal data, implementing whistle-blowing hotlines, big data, advising on special types of data processing (e.g. processing of data as part of a fraud investigation, processing of health-related data), conducting privacy compliance audits, filing notifications to data protection authorities, etc.)
— IT transactions (e.g. IT sourcing projects, cloud projects) and IT advisory work (e.g. advising on legal aspects of digital transformation, advising on electronic signatures)

Tom started his career in 2000 at Allen & Overy and joined CMS in September 2015. Legal 500 recommends Tom for Information Technology (tier 1) and EU Regulatory Data Protection (tier 1). Chambers Europe ranks Tom as "up and coming".

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We have a dedicated Lifesciences Sector Group, made up of over 150 lawyers across Europe, each of them focusing on healthcare and lifesciences, from his/her area of legal expertise.

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CMS DeBacker scrl, Chaussée de La Hulpe 178, 1170 Brussels, Belgium
T +32 2 743 69 00 – **F** +32 2 743 69 01

CMS DeBacker scrl, Uitbreidingstraat 2, 2600 Antwerp, Belgium
T +32 3 206 01 40 – **F** +32 3 206 01 50

CMS DeBacker Luxembourg, rue Goethe 3, L-1637, Luxembourg
T +352 26 27 53-1 – **F** +352 26 27 53-53

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