Global Life Sciences & Healthcare Forum 2023

Blurring Boundaries – Exploring the convergence of life sciences and law

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Welcome

A unique life sciences Forum brought the legal challenges created by the rapid pace of technological advances into sharp focus with sector focused sessions and informative workshops.

Experts from across the sector framed the incredible potential from digital and AI and called for the expertise of legal teams to take the ''regulatory handbrake'' off innovation that has transformative potential for healthcare systems and patients.

CMS's much-anticipated Global Life Sciences & Healthcare Forum 2023, co-hosted by Ellen Gielen, Roland Wiring and Gertie Lintjens, delivered a wealth of insight and ignited discussion about how regulatory frameworks can be tested and revised without compromising safety, security and compliance.

Blurring Boundaries – Exploring the convergence of life sciences and law heard from leading figures from pharmaceutical companies, cutting edge AI enterprises, legal experts and biotech organisations with a strong accent on debate and collaboration.

Marc Kaptein, Medical Director, Pfizer, revealed the unchartered territory he and his team had to tread during the pandemic as the company partnered with BioNTech to release a COVID vaccine and maximise its public uptake.

In a fascinating talk, he outlined the twists and turns of the inside story of how Pfizer struck a rapid deal with BioNTech by 'shaking hands' and then balanced the societal benefits of maximising its vaccination with legal constraints designed to control public promotion.

A willingness to break fresh ground legally, politically, scientifically and logistically was an integral part of the success story and he underlined to guests at the Forum, held in Amsterdam, that 'without blurring boundaries, we would not have got where we are today'.

Joep Rijnierse, Senior Medical Director at Amgen, highlighted its pioneering approach to work closely with patient groups to generate therapy promise across a complete health condition.

He said that the company's medical departments worked with internal and external legal advisers to find ways to manage constraints in the mission to enhance all areas of healthcare delivery to improve systems and outcomes.

Legal expertise is critical in shaping the landscape for AI developments and speakers from across the life sciences spectrum underscored the need for regulatory frameworks to evolve at pace.

Life sciences is experiencing seismic change and Thibault Helleputte, the Founder and CEO of DNAlytics, revealed that the BioGPT initiative was able to identify medical hypotheses from deep in the data of 15 million papers in PubMed library to give scientists unprecedented R&D leads.

The Forum was an opportunity to discuss how legal teams can use their skill and knowledge to ensure that regulatory frameworks did not impede progress and to explore fast and safe pathways for innovations to become working reality.

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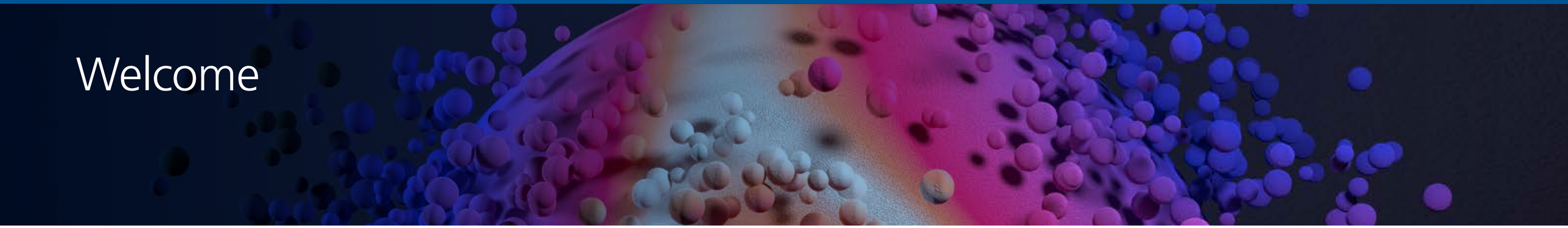
Welcome



Wouter Boon, Associate Professor in Innovation and Life Sciences at Utrecht University, emphasised the need to place legal aspects at the inception of the innovation process, observing that the sector was 'highly regulated for all good reasons but it means that radical innovation has a tough job.'

The Forum covered an impressive sweep of themes including AI, digital therapeutics, the challenges of multi-jurisdictional online pharmacies, the new EU medicines directive and co-creation with regulators.

"We had a great range of speakers who focused on advances and roadblocks across the life sciences sector and provided us all with some innovative and provocative approaches," said Nick Beckett, Global Co-Head of CMS Life Sciences & Healthcare Sector Group.

"It was a fantastic opportunity to discuss, explore and collaborate and the insights and learnings it generated will help us face global challenges in life sciences.

"We have to navigate global challenges such as sustainability, poverty, inequality, ageing populations; concerns about privacy with the use of data, concerns about ethics and the use of AI. To do that we need global perspectives and we believe that CMS as a firm, with 80 offices worldwide, is well positioned to navigate issues, foster collaborations and be a vital partner in moving life science innovation forward in the digital age."

Nick Beckett
Managing Partner, Beijing & Hong Kong
Global Co-Head of CMS Life Sciences
& Healthcare Sector Group
T +86 10 8527 0287/+852 2533 7818
M +86 186 1842 8030/+852 9756 5043
E nick.beckett@cms-cmno.com

Jens Wagner
Partner, Hamburg
Global Co-Head of CMS Life Sciences
& Healthcare Sector Group
T +49 40 37630 357
M +49 172 4356 708
E jens.wagner@cms-hs.com

Collaboration between legal teams and life science innovators is the key to unlocking potential

Life sciences innovation needs legal teams as critical partners to accelerate their benefits across the healthcare sector, a landmark Forum heard.

The importance of challenging legal frameworks and developing new regulatory strategies was brought into sharp focus at the CMS Life Sciences & Healthcare Sector Group's Forum 2023 ***Blurring Boundaries – Exploring the convergence of life sciences and law***.

Delegates from across the life sciences sector heard high profile speakers highlight how advances in health technology were outstripping regulatory frameworks, as well as discuss how legal teams can navigate road blocks to progress.

Experts from CMS, which has more than 80 offices worldwide, outlined how their practice was meeting the challenges to accelerate the introduction of new products, devices, processes and services that are powering the future of life sciences.

Ellen Gielen, Partner, Co-Head of Life Sciences & Healthcare CMS Netherlands, commented: "With new business opportunities, it is often necessary to amend existing models. Developments are moving rapidly but the laws cannot always keep up with those developments."

She highlighted the case of a Dutch supermarket group that wanted to extend its role as a certified drug store by dispensing medicines via an in-store video link direct to a prescribing pharmacist or doctor. The courts blocked the innovation because there was no provision in existing legislation to allow it.

"That was obviously disappointing, but the good thing was that the court saw it's benefit and said the law should be changed to permit the service. That change is going through now which demonstrates that the law can respond, although it will take time."

Roland Wiring, Partner CMS Hamburg, observed that new digital capabilities created potential, and problems, across geography and jurisdictions such as doctors in China being able to consult and prescribe with patients in Europe.

"There are a lot of questions around telemedicine treatments and how they are implemented with regard to data privacy questions, payment models and liability. It is our task as lawyers in advising start-ups or on new business models to find solutions, even if we are making new ground.

"For instance, we had a project with a virtual trials company that used AI to predict a medicine's outcome on patients and it was not clear that it would be classed as a service or medical device. How the legal rules apply, either existing ones or new ones, is a complex area that needs attention."

Analysts Deloitte cautioned that the shifting regulatory landscape and growing demands from healthcare providers posed significant challenges. Its 2023 Global Life Sciences Outlook framed the need for a legal focus as an integral part of innovation strategy.

Gertie Lintjens, Of Counsel, Co-Head Life Sciences & Healthcare CMS Netherlands, added that life sciences was an ever-broadening landscapes with challenges emerging from new technologies being deployed and new areas, such as nutrition plant-based medicines and service provision, being explored.

"We have pharma companies that are thinking out of the box about the potential of building business by offering integrated healthcare with medical devices, pharmaceuticals and care, which is not familiar territory, so you need to address issues around compliance," she says.

"There is a lot of innovation, change and challenge in the sector and it is exciting to be working with innovative companies and helping shape the future."

Rolling out the red carpet for life sciences' innovation

Industry experts call for greater regulatory flexibility to liberate transformational ideas.

Regulatory flexibility and legal expertise are key components to life sciences innovations reaching their full potential.

A landmark Forum that brought together key figures from the pharmaceutical industry, biotech, law, AI, start-ups and academia shared insights on the need to revise statutory approaches to liberate transformative advances.

CMS's Global Life Sciences & Healthcare Forum 2023, ***Blurring Boundaries – Exploring the convergence of life sciences and law*** heard a keynote address from Annemiek Verkamman, Managing Director of Hollandbio, calling for greater collaboration across life sciences and the law.

She emphasised that game-changing discoveries in the laboratory, transformative medical devices and new applications for AI were being held up not by doubts over their efficacy but by regulations that were created for a much slower, and less significant, R&D landscape.

"You can have great ideas, and many people in our sector are the brightest minds, but if you're not able to bring these innovations to the market, we won't benefit," said Annemiek, whose organisation represents more than 270 Dutch life sciences companies from start-ups to large pharmaceutical enterprises.

"To bring an innovation from the lab to the society is very difficult, which brings a lot of hurdles and especially for the frontrunners in biotech."

She highlighted issues around the use of organoids – stem cell cultures derived that provide fresh insights into the mechanisms of disease on human tissue – stating: "The potential is enormous but are we able to do it? Are we allowed and are we willing? These questions are coming up in biotech innovation all the time."

Annemiek also stressed that 70% of innovative life sciences products need regulatory approval while a report from analysts McKinsey commented that Europe's fragmented regulatory market was a drag on progress.

"The system is not ready for the future," she observed.

Integrating healthcare systems, smoothing out cross-geography bumps and navigating regulatory systems will advance the potential of life sciences to change lives, improve societal health and sustainability and boost innovation from start-ups through the R&D cycle so they can reach patients faster.

"That's where we need you guys. We need you to help and make it possible," said Annemiek, addressing the legal and regulatory audience at the Forum in Amsterdam. "How can we make these innovations happen because a lot of people in my sector know the system is not working. We need your in-depth knowledge, creativity and experience to roll out the red carpet for innovation."

Nick Beckett, Global Co-Head of CMS Life Sciences & Healthcare Sector Group, commented: "The Forum highlighted how important life sciences innovation is, not just to those involved in it, but to the wider society and how legal aspects are a crucial element of progress.

"The need for collaboration and a dynamic approach to legal and regulatory issues is something we focus on strongly and it is evident that it goes hand-in-hand with innovation."

Legal teams have a critical role to play from the start of life sciences innovation projects

Radical ideas to improve healthcare and its delivery need a guiding legal hand to break through regulatory barriers.

The healthcare revolution is forging ahead with advanced technology that is addressing everything from cancer to the common cold. The spectrum of disruption is diverse, ranging from stem cell engineering to AI innovation, but they have one challenge in common - the need to navigate existing regulations and laws.

Whether there are ethical or evidential barriers, technical or financial hurdles, a legal lens should be applied at the inception of every innovation process, a leading professor told a life sciences Forum.

Wouter Boon, Associate Professor of Innovation and Translation Studies at Utrecht University, told delegates from the pharma industry, medtech and the life sciences legal community: "Take into account legal issues, from the very start of an innovation process. Technology can only work if legal constraints are considered."

Professor Boon, whose research focuses on the dynamics and governance of emerging technologies, was speaking at CMS's Global Life Sciences & Healthcare Forum 2023, ***Blurring Boundaries – Exploring the convergence of life sciences and law.***

He highlighted that radical innovations had the ability to reshape society and the future of healthcare, but they were often slowed down from reaching potential, and patients, by regulatory regimes.

"Rules and regulations are present everywhere but particularly in health and life sciences," he added. "It is a highly regulated sector for good reasons, but it means that radical innovation sometimes has a tough job."

"For instance, there is a Catch 22 surrounding eHealth where there is a need for safety and efficacy data, but you can only generate that data if you can prescribe it and it is used sufficiently broadly. Similar Catch 22 situations exist across the field of emerging technologies in healthcare and life sciences.

"There are many more innovations in the pharmaceutical industry that are coming towards us, such as AI and 3D printing of biomaterials, but they need to break through existing regulatory regimes that might be resistant to new ideas.

"The Ubers of this world that change things without taking regulations into account in a 'Do First – Ask Permission Later' approach can achieve their goals in other sectors but that won't work in life sciences because you need medical validation."

The Forum was organised to promote debate and collaboration around how legal teams can work with start-ups and established companies to help realise their innovations.

"There was a lot to consider in the contribution from Professor Boon and the other speakers, but it was clear that we, as lawyers, have a critical role to play from an early stage," said Gertie Lintjens, Of Counsel, Co-Head of Life Sciences and Healthcare CMS Netherlands, who co-organised the Forum.

Challenging risk and rules: how the COVID-19 vaccine flexed its way through a daunting regulatory system

A compelling insight into how the COVID-19 vaccine found a way through regulatory constraints to rush to the world's defence has emerged at a legal Forum.

Pfizer's successful partnership with BioNTech was backed by years of ground-breaking scientific research and development but it still had to defy approval conventions to win public trust.

Marc Kaptein, Medical Director at Pfizer, revealed how the company had to take calculated risks to manufacture the vaccine, which was first delivered to a patient in December 2020 as part of the biggest global vaccination programme in history that has now passed 13 billion doses.

His reflections shed light on Pfizer's twin challenge of getting the science right and then being able to flex rules and regulations to win clinical approvals and public trust.

"We had been collaborating with BioNTech but the new CEO of Pfizer, Albert Bourla, who was appointed in 2019, still had to make the biggest gamble of his and the company's life within a year of taking over," he said at the CMS Global Life Sciences & Healthcare Forum 2023 ***Blurring Boundaries – Exploring the convergence of life sciences and law***.

The company decided against pursuing established vaccine platforms and, instead, authorised the investment of $2 billion into mRNA research that was already advanced in a flu vaccine but completely untested in public.

"He (Bourla) said: 'Listen, if we aren't going to do it, who is?' We just did it. This is like the moon shot, it is something we believe in and we think we can make a difference," said Kaptein.

Pfizer and BioNTech accelerated the vaccine's development on a handshake so that contract negotiations could take place alongside the R&D to avoid any delays to the process.

Kaptein recalled that the vaccine's first clinical trial of 44,000 patients hit an effectiveness level of 90% but the Pfizer team then faced a challenge of public perception as the vaccine and mRNA was novel.

"We observed a lack of trust in the Netherlands," added Kaptein. "They needed to see a face from the company, someone they could connect with who could explain how the vaccine was manufactured, where it came from and how it worked."

Kaptein was thrust into the spotlight with the task of reassuring the public but treading a tightrope of not breaching promotional regulations that were fixed in place but were not devised for a pandemic.

"It was a super intense period for me and the company but it is something we can look back on and say we made a difference," he added.

Nick Beckett, Global Co-Head of CMS Life Sciences & Healthcare Sector Group, said: "It was a compelling narrative on the importance of bold decision making and how rules and regulations can be tested, and how collaboration across all sectors can smooth the way in even the most challenging circumstances."

Forum speakers

Romain Alderweireldt
Senior Associate, CMS Brussels
T +32 2 674 85 74
M +32 475 85 98 24
E romain.alderweireldt@cms-db.com

Ellen Gielen
Partner, The Netherlands
Co-Head of Life Sciences & Healthcare Group
T +31 20 301 62 17
M +31 6 5248 2681
E ellen.gielen@cms-dsb.com

Gertie Lintjens
Of Counsel, The Netherlands
Co-Head of Life Sciences & Healthcare Group
T +31 20 301 62 30
M +31 6 5382 2967
E gertie.lintjens@cms-dsb.com

Shuna Mason
Partner, London
T +44 20 7367 2300
M +44 7768 335474
E shuna.mason@cms-cmno.com

Gabriela Staber
Partner, Vienna
T +43 1 40443 4850
M +43 664 60443 4800
E gabriela.staber@cms-rrh.com

Christoph Willi
Partner, Zurich
T + 41 44 285 11 11
M + 41 79 614 8281
E christoph.willi@cms-vep.com

Roland Wiring
Partner, Hamburg
T +49 40 37630 309
M +49 172 742 2485
E roland.wiring@cms-hs.com

Jörn Witt
Partner, Hamburg
T +49 40 37630 339
M +49 172 715 8445
E joern.witt@cms-hs.com

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