PRESS RELEASE

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Subject	Annual CMS Global Lifesciences Forum tackles industry hot topics

CMS Global Lifesciences Forum 2015 in Frankfurt tackles the industry's hottest topics

- There are major M&A opportunities in the lifesciences industry, particularly in the fragmented medical device sector
- eHealth and mHealth devices and apps are changing the way patients interact with their doctors and medicine
- Big data has great potential to help the medical industry, but must overcome data protection risks before being fully utilised
- Changes to the way trade secrets are defined and regulated across the EU could have implications for clinical trials

The CMS Global Lifesciences Forum 2015 brought together senior executives involved in Lifesciences from around Europe as well as other experts to discuss the issues driving the industry. The forum explored M&A, liability risks, marketing and distribution, eHealth and mHealth, big data, nutraceuticals and the protection of trade secrets.

Successfully managing deals

The M&A panel looked in detail at the medical devices and the pharmaceuticals market. The panel referred to M&A as 'the lifeblood of the industry' and stressed that consolidation and partnerships are vital to continued growth and success.

According to Dr Max Gisbert Kley, Member of the Management Board at the Freudenberg Medical Group, a family company that produces medical devices and components, the deal environment for medical devices, which has been recovering since it was hit by insecurity surrounding the Affordable Care Act in 2011, looks to be increasingly favourable.

Major opportunities can be found in the fragmented medical devices sector as it consolidates to achieve scale and counter balance consolidation on the healthcare provider side. Market leader Medtronic holds an estimated 8% market share, followed by Johnson & Johnson. While a handful of companies take a market share of 1%−3% each, the remaining share of about 45% was shown to be held by thousands of smaller firms. Companies are also looking to expand their footprint and break into emerging markets.

In her presentation, Dr Birgit Reitmaier, Director Global Business Development at Merck, a leading global pharmaceutical company headquartered in Germany, showed that the pharmaceutical market has seen an overall decline in M&A since the financial crisis. Oncology, however, has been an area of

continued strength, with deals remaining at the 8−9 per year mark. The strength of the oncology sector has encouraged companies to spend more on early stage assets. This dynamic is leading the market towards earlier deal making and greater risk taking, albeit for better rewards.

Effectively handling product liability risks

Eva Schothorst-Gransier, Partner at CMS Utrecht, and Chris Tait, European Life Science Underwriting Manager at Chubb Insurance, held a lively discussion on 'effectively handling product liability risks'. Although Europe is trying hard to harmonise legislation, they showed that courts in several jurisdictions are struggling with the interpretation of the applicable European Directives. This has been emphasised since the multi-jurisdictional cases of PIP and Boston Scientific. The panel found that at present the risk environment is overwhelmingly friendly to the consumer. This follows from tightening legislation as well as recent jurisprudence from the European Court of Justice. The exposure to liability is significant. As a consequence, manufacturers must focus on compliance, spend properly during development and avoid cutting corners in order to avert large claims. Aside from agreeing on contractual indemnities (as far as possible), taking out proper insurance is recommended.

Going digital

During the panel on marketing and distribution in lifesciences, Dennis Kaben, Legal Director at Google Germany GmbH, showed the forum the importance of online and mobile advertising to reach customers in a world that is increasingly connected and where already half of all current devices are mobile. Sandra Hoyer, Head of Consumer Health and Pharma at German telecommunications firm Deutsche Telekom, stressed that one of the biggest advances in lifesciences this decade has been the advent of smartphone technology. Patients can now track a large number of variables through sensors in their phones. This advance in data collection has driven innovation in the eHealth and mHealth sectors. Devices will continue to get smaller and more inconspicuous. A milestone of this trend is a 'digital pill' which was recently given FDA approval. This medication combines a regular pill with an ingestible sensor. With the addition of an adhesive patch and a mobile application, this solution is able to track ingestion of the pill as well as vitals and then transmit data from within the body. Klaus Rupp, Head of Unit Care Management at Techniker Krankenkasse, discussed telemedicine and the benefits this could have for busy patients. Although telemedicine is far from becoming the norm, it is certainly a leap forward for eHealth.

It's all about the cloud

Big data was also an important discussion point this year. The use of big data is certainly attractive to the pharma industry, the idea being that it can be accessed at will and used to diagnose health issues and discern best treatment practice based on the huge amount of historic data currently stored. Issues of data protection and methods of storage sparked lively debate between Dr Matthieu-P. Schapranow, Program Manager E-Health at the Hasso Plattner Institute, the German university specialised in IT Systems Engineering, and Michael Dörr, Director of Supplier Relations Central Eastern Europe at IMS Health, a global information solution provider for the pharma and healthcare industries.

Algorithms are being produced that can sift through data more efficiently than ever. These algorithms can provide accurate solutions to health issues based on historic cases with a high degree of reliability,

according to Dr Schapranow. It was, however, pointed out by Mr Dörr that with such intelligent algorithms there are dangerous implications for data protection as they risk unintentional de-anonymisation. Dr Schapranow suggested that the issue of de-anonymisation could be addressed by patients providing authorisation that medical data may be used in such circumstances, a similar concept to a donor card. Another contentious point on the subject of big data was the clash between cloud storage and local storage. Cloud storage seems most attractive as large amounts of data need not be stored on site. It was argued, however, that cloud storage for lifesciences involves long data transfer times at hospitals or labs due to sheer volume of data, whereas data processing on site would only require the transfer of comparably small algorithms.

Legal challenges of nutraceuticals

Simone Pelkmans, General Counsel Foods − Baking, Cooking & Spreads and Dressings at Unilever Netherlands, and Pascal Buergin, Head of Law and Compliance at Bayer Consumer Care AG, discussed a fairly new branch of the lifesciences tree: nutraceuticals, i.e. the role that foods and nutritional supplements play in the industry. There was a focus on the regulatory hurdles faced by multinational food companies producing nutraceuticals when marketing brands across multiple jurisdictions. They highlighted that the lack of global harmonisation when it comes to marketing and advertising health benefits must be addressed for the sector to flourish.

Protecting business secrets

The final topic of the day was protecting trade secrets. At present, there is no harmonisation within the EU for trade secrets best practice, as discussed by Dr Nikolas Gregor, a Senior Associate from CMS Hamburg. There is currently draft EU legislation that would ensure trade secrets are treated as an intangible asset throughout the EU. The legislation would lead to substantial changes of the legal framework in many member states, especially when it comes to defining a trade secret. Currently, the suggested definition is ‘know-how and business information’ that meet the following requirements: It is not generally known to those in the specific field, it has commercial value because it is a secret and that reasonable steps be taken to keep it a secret. These rules would, of course, have implications for the development of new drugs and, as addressed by Dr Thomas Hirse, Partner at CMS Duesseldorf, for clinical trial data.

Under the proposed definition, clinical trial data would be classified as a trade secret. This would be problematic for the European Medicines Agency (EMA) initiative which aims to increase transparency. According to its Policy No. 0070 that came into force on 1 January 2015, EMA proactively publishes, through an IT system, clinical study reports supporting a new marketing authorisation application or in the course of a post-authorisation procedure. This will allow patients and patient groups, but also competitors, to review clinical trial data as well as pre-clinical data and other sensitive proprietary information. This causes a conflict as such data and information are clearly regarded trade secrets under the draft EU directive. However, the EMA does not regard such data and information (including clinical trial data) as ‘commercially confidential information’ for which the clinical study reports can be redacted.

At the end of the day, Willem Hoorneman, Partner and Head of the CMS Lifesciences Group, thanked the audience, speakers and panellists by saying: ‘We were proud to see so many industry experts at-

tend the forum. The points discussed are at the cutting edge of our industry and will be shaping it for years to come. We look forward to seeing the innovative ideas discussed over the course of the day be implemented in the coming year with great excitement.'

A full conference report will be available soon. Please contact us, if you would like a copy.

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Notes to editors:

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