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CMS Global Lifesciences Forum 2015

Shaping the future through innovation and collaboration

December 2015

Introduction

We were proud to see so many industry experts attend our Forum. The points discussed are at the cutting edge of our industry and will be shaping it for years to come. We are excited to see how the innovative ideas discussed over the course of the day are implemented in the coming year. Thank you to everyone who took part in the Forum, it was an extremely thought-provoking day and we look forward to welcoming you to our Forum next year.

On 9 November 2015, Lifesciences professionals from around the world gathered to discuss the industry's hottest topics at the CMS Global Lifesciences Forum 2015. In this report, we summarise the challenges facing the sector today and the possible solutions offered to help you overcome them. Many of the industry experts also highlighted the need for continued innovation and reminded us that the future is already, at least partly, here.

Executive Summary

M&A activity: partnerships are the way forward

Following the economic downturn of 2008, the market had been in decline. We are, however, seeing recovery kick in. The pharmaceutical market now sees more risk for higher rewards as companies look at early stage assets to solve their competition issues. To flourish in the highly regulated, and fragmented, medical devices environment, companies must consolidate to grow. Suppliers need to offer the whole package on a global scale to stay competitive.

Liability and risk: compliance in a consumer-friendly market

The medical industry is under increasing legal pressure, particularly due to a consumer-friendly risk environment. We can see this from restrictive legislation and two recent landmark cases: the PIP (Poly Implant Prothèse) case, concerning a French company that supplied thousands of women with defective breast implants, and Boston Scientific which dealt with pacemakers and defibrillators. The dangers of liability costs are beginning to outweigh risk. It is important that manufacturers focus on compliance and spend more in the R&D phase to save money down the road.

The internet and smartphones: changing pharmaceutical marketing

Now that people are almost constantly online and more than half of all connected devices are smartphones, it has never been easier to understand consumer needs and reach them wherever they are. Google revealed that 1 in 20 searches is health-related, meaning there are huge opportunities in targeted advertising. With the smartphone revolution, an increasingly powerful new set of tools – from attachments that can diagnose an ear infection or track heart rhythms to an app that can monitor mental health – can complement our use of doctors, cut costs, speed up the pace of care and give more power to patients.

eHealth: the future is now

A number of devices that were once just science fiction are now being used in the Lifesciences sector. Surgeons can use Google Glass to see patients' vital signs while they operate, smartwatches can track a whole host of variables and report back to the doctor, contact lenses can measure blood sugar levels and there is even a pill that can track basic bodily functions from inside the body.

Big data: changing diagnosis and treatment

With better technology comes a smarter use for the data produced. Computer scientists can now produce complex algorithms that allow for huge amounts of data to be analysed quickly. Such analysis allows doctors to diagnose and treat patients quickly without having to wait for data to be sent to a lab and returned. This does, however, have implications for data protection.

Nutraceuticals: an emerging sector

Nutraceuticals are nutritional products that provide health and medical benefits, and the market for them is growing. Unfortunately, a lack of global harmonisation is hindering innovation in the sector. Strict EU regulation and a precarious legal environment in the US means that cross-border marketing is a costly struggle.

Trade secrets: guidelines needed

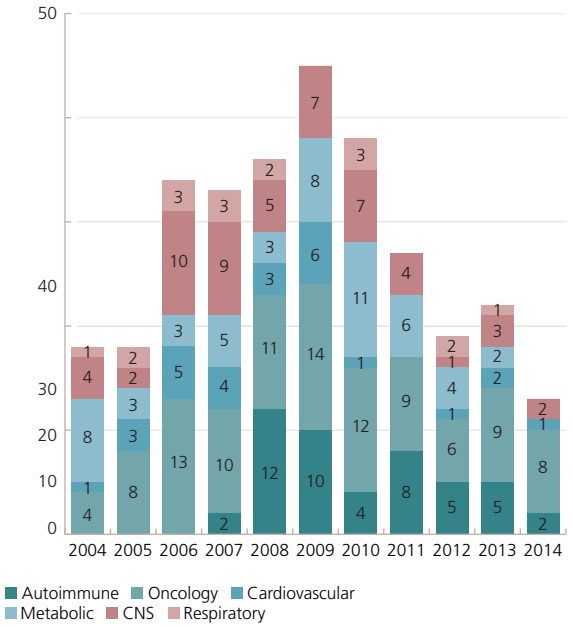
EU regulation on trade secrets is changing. However, even if the new Directive is implemented, it still offers little in the way of concrete definitions and guidelines. The Directive will certainly also have an impact on the current discussion around publication of clinical trial data and the new European Medicines Agency (EMA) transparency policy.

M&A and alliances in Lifesciences: successfully managing deals

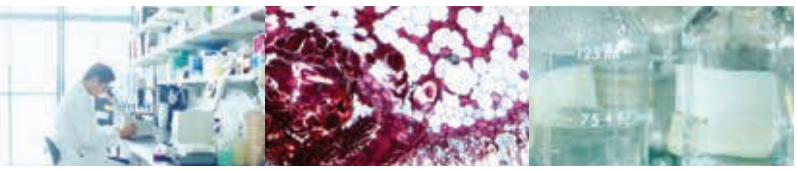
M&A was referred to as 'the lifeblood of the industry' and it was found that consolidation and partnerships were vital to continued growth and market success.

In her presentation, Dr Birgit Reitmaier, Director of Biomarker and Technology Global Licensing at Merck Serono, showed that the pharmaceutical market has seen an overall decline in reported M&A deals since the global economic crisis of 2008-10. Despite the decline, oncology has been an area of continued strength, with deals remaining at the eight to nine per year mark.

Acquisition and licencing deals of Big Pharma (2004 – 2014)
Number of reported deals



Source: Pharma Ventures 2014 Report



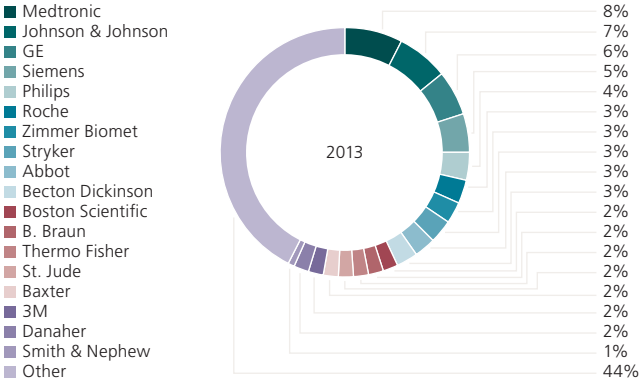
The strength of the oncology sector, along with fierce competition for viable acquisition targets, is driving companies to spend more money on early stage assets. 72% of oncology drugs fail in Phase II, making the trend a risky one. What we are seeing now is earlier deal making and greater risk taking, albeit for larger rewards.

The deal environment for medical devices is looking to be increasingly favourable, according to Dr Max Gisbert Kley, member of the Management Board at the Freudenberg Medical Group, a family-owned company that inter alia produces medical devices and components. The medical devices market has been recovering since it was hit by insecurity surrounding the Affordable Care Act in 2011. There are major opportunities in the sector as it consolidates to achieve scale, and balance the consolidation on the healthcare provider side. Market leader Medtronic holds an estimated 8% market share, followed by Johnson & Johnson. Market share then drops quickly to the 1%-3% range, with about 45% of the market held by thousands of smaller firms.

Arbitration clauses 2007–2014

Market Size 2014: USD 345bn

Growth: ~6% p.a.
(EU 4% | US: 6% | China 18%)



Source: Kalorama 2013 | Epicom | Own estimates

Some companies are shedding non-performing assets in order to focus on core competencies, such as Johnson & Johnson's sale of Cordis. Companies are also looking to expand their footprint and break into emerging markets.

The importance of emerging markets was made clear by Dr Kley, which have different requirements to developed markets. This means the development stage can be even lengthier, with companies having to test whether their product is suitable for multi-market release. Emerging markets have a need for sturdy, reliable products which are also cost effective. With increasingly strict regulatory demands, smaller companies are finding it difficult to break into these markets as this requires both regional and portfolio expansion.

Dr Kley went on to say: "Large multinationals are growing, and looking to consolidate their supplier base. They want fewer suppliers offering higher quality products, with quality systems in place to support them. Smaller specialised suppliers can no longer keep up with the demand from the bigger players." A broad product offering can only get a company so far. Multinationals are also looking for international support as they move into emerging markets, which means that device suppliers must look to expand their global footprint when making deals in order to remain competitive.

Effectively handling product liability risks

The panel looked in detail at the rocky landscape of liability and risk in the Lifesciences industry. Eva Schothorst-Gransier, partner at CMS Utrecht, pointed out the increasing legal pressure for the medical industry. Apart from recent case law, the European Commission has recently started trilogue negotiations to revise the Medical Devices and Diagnostics Directives. The new revisions would potentially mean that manufacturers not only have to have their product file and quality system tested, but must have a physical sample tested as well. In many cases, this will create more work than is currently required by the so-called interim measures already imposed.

Although Europe is trying hard to harmonise legislation, the panel showed that courts in several jurisdictions are struggling with the interpretation of the applicable European Directives. For example, the PIP[1] case saw patients start proceedings against the notified body across Europe. Although in Germany it was found that the notified body did not violate its duty of care, in France it was found that it did. At appeal, the judgment of the French court was reversed. However, the scope of the liability principle according to the Medical Devices Directive still remains vague and unclear. The European Court of Justice needs to provide further guidance, and it will, since the German Supreme Court referred a question to the European Court in the PIP case about the scope of the notified body's responsibilities.

In the Netherlands, patients took a different approach and sued the hospital – the manufacturer's negligence was attributed to the hospital because the manufacturer was bankrupt, the entire line of devices was defective and the hospital, rather than the patient, was regarded as an expert.

In Boston Scientific, the court found the pacemaker to have an increased failure rate at nearly 20x higher than the normal rate. However, the claimants were unable to prove that the pacemaker in question was defective as the device had been disposed of. The European Court applied a broad definition of a defect, requiring the claimants to prove that the product was part of a series or group which is subject to a potential defect. They also stretched the definition of damages to include costs relating to the replacement of a defective product, under the condition that such an operation is necessary to overcome the defect.

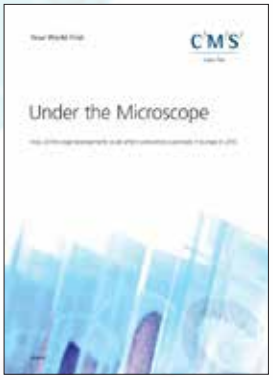
Eva Schothorst-Gransier said: "Although from a consumer perspective the Boston Scientific judgment may sound fair, it potentially imposes a higher level of risk on the whole medical devices sector. Manufacturers could now be confronted with risk liability claims not only for defective products, but also for potentially defective products. Care should be taken to ensure that this line of argumentation is not easily applied to other kinds of medical products."

The risk environment is increasingly friendly to the consumer, so manufacturers must focus on compliance, spend properly during development and avoid cutting corners. By doing so, large claims can be avoided. As Chris Tait, European Life Science Underwriting Manager at Chubb Insurance, said: "Manufacturers shouldn't concentrate on cost efficiency in production as the higher costs of claims handling is potentially linked to cost reductions in production."

He added: "We advise not to handle the product liability risk on a purely contractual basis with technical partners and sub-suppliers as it is not always possible to achieve sufficient recourse against such partners."

Mr Tait noted that this is especially true when dealing with suppliers from emerging markets.

[1] PIP or Poly Implant Prothèse was a French company that supplied thousands of women with defective breast implants.



Under the Microscope

The CMS publication *Under the Microscope* examines some of the key legal developments in the Lifesciences sector in 2014 across Europe, including: Regulatory/ Competition; Compliance/ Transparency; Intellectual Property; Product Liability. We also consider what these developments, particularly the opportunities and trends, might mean for you and your business. A new booklet covering 2015 / 2016 will be published in February 2016.

Distribution and marketing of drugs

The 2015 edition of *Distribution and Marketing of Drugs,* a guide to the distribution and marketing of drugs in 28 jurisdictions around the world, has recently been published. Each chapter provides an overview of the legal framework governing distribution and marketing of pharmaceuticals, including: pre-conditions for distribution; licensing; wholesale distribution; marketing to consumers; marketing to professionals; and engagement with patient organisations. CMS contributed information on four jurisdictions: Austria, Italy, The Netherlands and Russia. Further information on the global guide is available: www.uk.practicallaw.com.

Lifesciences webinars 2016

Also in 2016, the CMS Lifesciences sector group will organise a webinar series. As in 2015, we will host eight webinars on various Lifesciences topics. The 2015 webinars covered the legal aspects of trending topics across the full spectrum of the Lifesciences industry: (i) medical devices regulation; (ii) product liability in Lifesciences; (iii) smart health legal impacts; (iv) SPC – case law; (v) personalised drugs; (vi) trade secrets; (vii) distribution models; (viii) clinical trial regulations.

Each webinar lasts one hour and is held in English. Participation is free of charge. The invitation for the webinar series will be sent in January 2016.

Lifesciences in the internet age

Going digital: online marketing and distribution in Lifesciences

Dennis Kaben, Legal Director at Google Germany GmbH, explained to the Forum how online and mobile advertising can help reach consumers in a world that is becoming increasingly connected and where half of all current devices are already mobile.

People no longer connect to the internet, they live on the internet. Gone are the days where a family gathers in front of the same screen, the multi-screen home is already reality. The health industry must adapt to this change in consumer behaviour to reach consumers who see the internet as an increasingly important source of information on health issues.

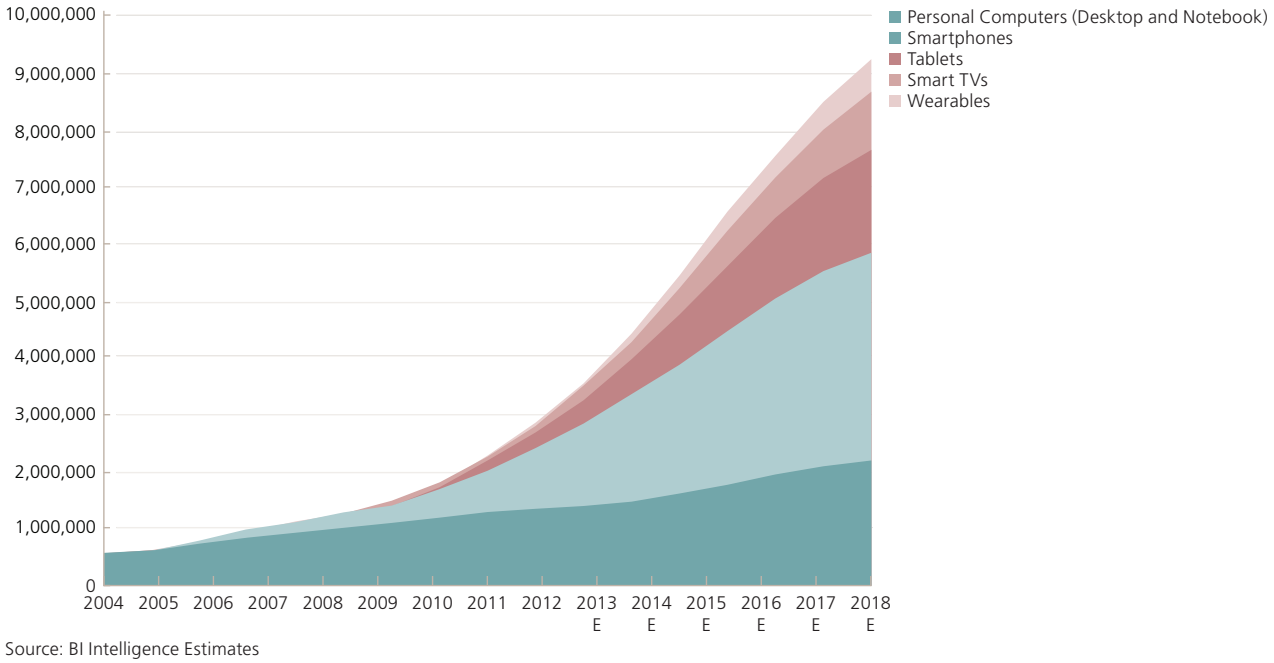
According to Google, 1 out of every 20 searches is health-related. This amounts to a large number of searches when in Germany alone there are 14 million per day in this area. Data analysis on this scale allows for two major advances in the sector. Firstly, pharmaceutical companies and device manufacturers can tailor adverts to the interests and needs of specific target groups. Secondly, it is possible to engage with a wider audience to distinguish what kind of devices and solutions are going to be popular with the public.

eHealth: game changer for the Lifesciences industry?

Last year's Forum rightly emphasised that the medical devices industry would have to embrace the benefits of

Global Internet Device Installed Base Forecast

Number of devices in use (in thousand)



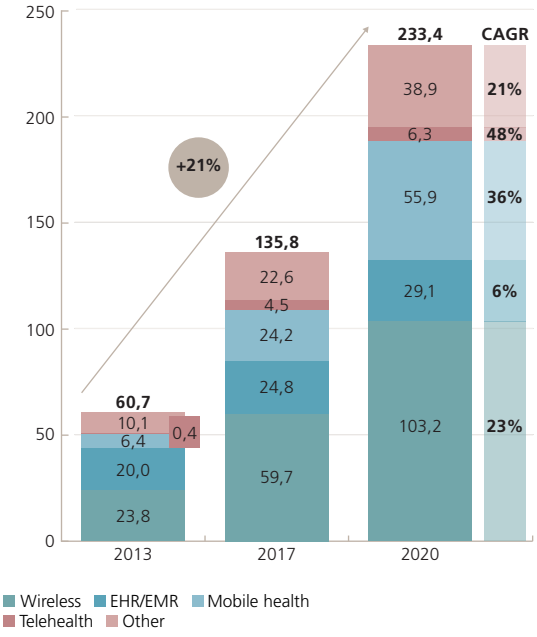
Source: BI Intelligence Estimates

eHealth. This year's Forum showcased some of the ways in which the industry has done this spectacularly.

Devices such as Google Glass are now being used in the medical sector. Medical professionals can wear the device and not have to break concentration to check on a patient's vital signs as they are clearly visible in their peripheries. Contact lenses are now able to measure the blood sugar level in a patient's tear liquid.

Sandra Hoyer, Head of Consumer Health and Pharma at German telecommunications firm Deutsche Telekom, also 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.

Digital Health Market 2013 – 2020
in bn USD



Source: Arthur D. Little, Succeeding with Digital Health

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, a major German health insurance fund, 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. Telemedicine, the fastest growing sector within the digital health market, is the delivery of health-related services through telecommunication technologies. However, it is still far from being common practice, given European regulation around diagnosis being made without a doctor present.

It's all about the cloud: big data in Lifesciences

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 the huge amount of historic data currently stored can be accessed at will and used to diagnose health issues and develop treatment practice. Issues of data protection and methods of storage sparked a spirited debate between Dr Matthieu-P. Schapranow, program manager eHealth at the Hasso Plattner Institute, a German university specialising 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 such intelligent algorithms have 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 issue with big data is the clash between cloud storage and local storage. When tests are conducted, a huge amount of data is produced – a simple DNA test returns around 750 GB of data. This presents storage problems which make cloud storage attractive because large amounts of data need not be stored on site. However, cloud storage in the Lifesciences sector can be a double-edged sword because it involves long data transfer times, which could potentially have a negative impact when treating life-threatening illnesses. Dr Schapranow advocated on-site storage and processing because it would only require the transfer of comparatively small algorithms.

Nutraceuticals and other borderline products: key legal challenges

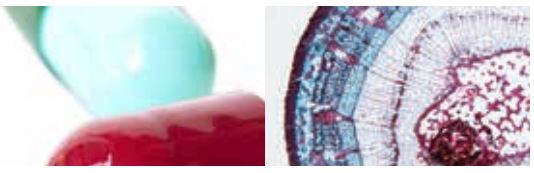
Simone Pelkmans, General Counsel Foods – Baking, Cooking & Spreads and Dressings at Unilever Netherlands, and Pascal Buergin, Head of Law and Compliance at Bayer Consumer Care AG, held a lively discussion on a fairly new branch of the Lifesciences tree: nutraceuticals, i.e. the role that foods and nutritional supplements play in the industry. They focused on the regulatory hurdles faced by multinational food companies producing nutraceuticals when marketing brands across multiple jurisdictions.

Nutraceutical developers have to work within a legal framework that is becoming increasingly regulated. Any health benefits advertised must be backed by solid science and clinical data. Unfortunately, there is no global standard and at present companies will usually take US and EU law as standard. While US law is fairly lenient, the regulatory framework in the EU is incredibly complex and is focused on mitigating risks.

In both the US and the EU, the trend is that the legislation and regulatory density for nutraceuticals are comparable to those for self-care medication. This is only an early step on the road and legislation will become stricter as a result of food scandals and a drive for increased consumer protection.

Mr Buergin said: "An additional challenge in the nutraceutical business is the ageing population. This will result in a demand for new and innovative products that fit their needs. Also, consumers want to be informed transparently about products to be able to make their own decisions."

Both Ms Pelkmans and Mr Buergin agreed that the lack of global harmonisation is a major issue in the sector when it comes to developing and marketing products. For the continued growth of this young industry, there needs to be a focus on bringing global regulations in line, and backing for regulation that is conducive to innovation.



Protecting business secrets despite the push for maximum transparency

The final topic of the day was protecting trade secrets. Dr Nikolas Gregor of CMS Hamburg discussed the present lack of harmonisation within the EU for trade secrets best practice.

There is currently a draft EU Directive 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.

At present, the suggestion is that it is defined as "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 are taken to keep it a secret.

These rules would, of course, have implications for the development of new drugs and for clinical trial data, according to Dr Thomas Hirse, partner at CMS Duesseldorf.

Under the proposed definition, clinical trial data would be classified as a trade secret. This is problematic for the European Medicines Agency (EMA) initiative to increase transparency. According to its Policy No. 0070 that came into force on 1 January 2015, the 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 as 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.

While the impact of the suggested Directive may not be that huge, the new rules will certainly lead to an improvement in many member states with regard to confidentiality in trade secret litigation as well the remedies available. The new Directive will also be a good opportunity for Lifesciences companies to reassess their safety net, to ensure that their trade secrets are properly protected and compliant with legal requirements.

The suggested definition in the draft Directive creates a requirement for companies to take sufficient measures to protect their secret information – otherwise they may not benefit from legal protection for their trade secrets. However, uncertainty around the Directive means there is no clear guidance on what measures should be taken to ensure secrecy. We can take examples from the US where they already have the requirement to objectively undertake reasonable steps to keep information secret so that it is protected as a trade secret. There are two main aspects in the US. Firstly, contractual aspects such as non-disclosures and non-compete obligations, which however must be compliant with labour laws. Secondly, the actual practice of secrecy is important such as ensuring documents are marked as confidential, limiting the circle of people that are privy to the information and correctly storing or password-protecting files. These are just a few of the many possible measures that would have to be taken.

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