Increasing Regulatory Burden on UK Pharmaceutical Companies Fuels Need for Technology Solutions to E-Discovery

Pharmaceutical companies in the UK are facing rising litigation risks and growing regulatory pressures on multiple fronts.

In March 2017, the Competition and Markets Authority (CMA) announced an investigation into large pharma firms regarding potential anti-competitive agreements to inflate the price paid by the National Health Service (NHS) for certain lifesaving drugs.

This came on the heels of an effort launched in January 2017 by the UK Department of Health to create a panel of law firms who will be charged with pursuing litigation against companies in the pharma industry. The department announced their intention is to "establish a panel of law firms to act for, and provide advice to, the Department of Health in connection with Civil Litigation Arbitration and Mediation against companies in the pharmaceutical industry."

Beyond these recent news developments, the pharma industry is positioned to face growing litigation and regulatory scrutiny due to other global trends. For example, the Healthcare Internet of Things offers exciting opportunities to benefit health care delivery in general and the drug supply chain in particular; but it also triggers new concerns about the electronic transfer of personal data related to patients' medical conditions. Pharma companies and their distributors are increasingly collaborating with doctors and their patients through social media and other evolving communications channels; but these new vehicles raise myriad challenges to comply with data security and privacy regulations.

Managing E-Discovery

This growing regulatory and litigation pressure on UK pharma companies raises the stakes on how corporate executive teams manage electronic data that resides on email servers and other data repositories. In the heat of a government investigation or a legal battle, it's likely that a company will be called upon to conduct e-discovery—review vast troves of electronic data and produce responsive evidence—under incredibly tight deadlines.

Moreover, these e-discovery challenges are even greater for pharmaceutical companies because they often require them to harvest data from restricted information sources that hold complex clinical trial records, adverse reaction findings, and highly confidential sales analysis reports.

Corporate legal executives are typically assigned the burden of managing a pharma company's e-discovery obligations during a regulatory investigation or a legal dispute with another company. Experts advise that a few key strategies can help pharma executives better manage their e-discovery responsibilities:

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1. Know Your Data

It's important to take a pro-active approach to the way you manage information throughout the organization. Start by understanding the underlying data landscape: Are your company's emails archived? Do you use cloud servers or on-premises servers? What communications platforms do you use? Then make sure you have a clear information governance policy that establishes a data retention schedule for each type of data in your organization. This will aid with e-discovery management when the time arises and will provide you with a clear line of defense if specific data troves are unavailable to regulators or litigation adversaries.

2. Beware Data Privacy

Evaluate how relevant privacy laws (International, EU, UK) might impact the e-discovery process. For example, you need to ensure that your team is in compliance with the new EU-U.S. Privacy Shield standard. A best practice is to consult outside counsel for a thorough assessment of privacy requirements that can impact the data collection workflow. For example, your team must strictly comply with relevant data privacy laws, such as the process used to transport privacy-restricted data between locations from which it is collected and processed.

3. Get Your Workflow Right

It's crucial to have sound quality-control procedures in place for your entire e-discovery process. To make sure that you're prepared for a regulatory or litigation demand, conduct thorough quality-control checks on accuracy and defensibility. Document your e-discovery activities in a chain-of-custody form that details the data source, the physical description of media onto which data is transferred, and steps taken throughout the workflow. Also, your team should store all collected data in a redundant environment to protect against data loss.

These initial strategies will help your corporate legal team deploy an e-discovery management approach that will help you better cope with the daunting challenges of managing electronic data in a regulatory investigation or legal dispute. But the reality is that the task is simply too great to be handled with manual systems.

E-Discovery Tools

Savvy UK pharma companies are managing this surge in electronic data management pressure by leveraging software that helps them deal with huge amounts of data and extracts relevant information.

E-Discovery software collects, extracts and organizes data from all kinds of servers and devices. Importantly, these tools allow in-house teams to discreetly conduct an e-discovery project—collect sensitive data, search for the responsive evidence needed and produce it to the regulators—without involving too many internal or external professionals who might not need to know about the inquiry that is underway.

Many UK corporate executives have discovered the benefits of cost-efficiency and risk management that can be realized by using a single software platform to manage the entire spectrum of evidence collection, processing, review and production:

- **Collection**—Corporate teams can leverage the power of software tools to quickly gather the universe of potentially relevant data from their various information systems. For example, the right e-discovery software products can ensure data is not being altered, dropped or missed during collection. Forensic data collection capability is especially valuable in an e-discovery software solution, as it provides not only the strongest level of collection stability but also shows that it's focused on compliance.
- **Processing**—All data that was collected now gets extracted and turned into information that can be culled down for greater relevance. Speed and accuracy are at a premium here and the ideal software solution should be one that can easily and affordably scale using existing hardware to achieve fast processing speeds. The single criterion that varies the most across e-discovery vendors is accuracy, so make sure you're using a tool that has a proven track record for not only speed and culling rates, but also thoroughness and accuracy of its processing engine.
- **Review**—The best e-discovery software tools help you quickly determine what electronic evidence you now have that will be responsive to the regulatory demand you received. The technology should be able to categorize, refine and bucket the data for you by using functions such as keyword searches and culling. In addition, your software should be able to quantify and present which documents did and did not meet your search criteria for responsiveness to the regulatory or litigation request.

- **Production**—Finally, you should be able to export data out of the system in various formats without incurring an additional expense or using a third-party application. Today's productions come in many formats and some may never see paper, so your e-discovery software has to be capable of handling not only the traditional production duties of redacting, printing and numbering—but be able to produce data in its many formats and iterations. Having said that, the UK and EU regulatory worlds are far from giving up on paper, so your software tool should also make it easy to click and print.

The use of e-discovery software has become increasingly commonplace in the UK as a way to automate the collection, processing, review and production of electronic data in a cost-efficient and reliable manner.

Conclusion

The management of electronic data is a complex and time-consuming challenge for corporate legal executives in any industry. These challenges are especially acute for UK companies in the pharmaceutical industry, which are particularly subject to rising regulatory and litigation pressures. The good news is that sophisticated software tools, such as AccessData's AD eDiscovery®, can help pharma companies mitigate risk, ensure compliance and improve response efficiency to increasing e-discovery demands.

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Visit us online:
www.accessdata.com

Global Headquarters
+1 801 377 5410
588 West 300 South
Lindon, Utah

North American Sales
+1 800 574 5199
Fax: +1 801 765 4370
sales@accessdata.com