QUILTER CHEVIOT

RESPONSIBLE INVESTMENT

A clean bill of health?: Product safety and litigation risk in the pharmaceutical and healthcare industries

Across Quilter we have identified three thematic engagement priorities. This is part of our human rights theme.

The idea of human rights is as simple as it is powerful: that people have a universal right to be treated with dignity. Every individual is entitled to enjoy human rights without discrimination – whatever their nationality, place of residence, sex, national or ethnic origin, colour, religion, language or any other status. Human rights are interrelated, interdependent and indivisible[1].

SDG Alignment

> *"It is easy to get a thousand prescriptions, but hard to get one single remedy."*
>
> Chinese Proverb

1 United Nations backed Principles for Responsible Investment

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Managing product safety is key for companies as it can impact financial prospects, as well as trust amongst consumers, suppliers, and investors. Product safety breaches are described by the US Consumer Product Safety Commission (CPSC)[2] as the unreasonable risk of injuries and deaths associated with consumer products. Healthcare and pharmaceuticals companies are especially vulnerable to product safety issues. Failure to undertake adequate testing for drugs and medical equipment can lead to recalls, which not only have an economic impact but also reputational ramifications. In the most extreme cases, the products can lead to the injury and death of customers – which may result in litigation.

Litigation can be hugely expensive. For perspective, the largest ever corporate fines in US history have been awarded against pharmaceutical companies. The litigation process may take years, and until the case is resolved there is a degree of uncertainty that in some instances may have implications for the company's valuation. Additionally, the reputational damage of these high-profile cases may become embedded in the customer's vision of the brand. Finally, there is the human cost when drugs or medical equipment fail the patient.

Under certain jurisdictions if a group of people are affected by the same issue, they can collectively sue the offender. A class action lawsuit is a type of lawsuit where one of the parties is a group of people who are represented collectively by a plaintiff. Specifically in the US a Multi-District Litigation (MDL), refers to a federal legal procedure designed to facilitate large or complex cases as is the case with product liability suits. For example,[3] in 2018 Johnson & Johnson was ordered to pay nearly $4.7bn (£3.58bn) in damages to 22 women concerning their claim that the company's talcum powder contributed to them developing ovarian cancer, and further lawsuits might follow. In 2012, GlaxoSmithKline paid $3bn (£2.46bn) after pleading guilty to the unlawful promotion of prescription drugs and failing to report safety data to the Food and Drugs Administration (FDA).[4]

Engagement

The engagement programme targeted our most material holdings in the health care equipment & services and pharmaceuticals industry groups, focusing on their approach to risk regarding litigation and product safety issues. Specifically, we have identified product quality and safety, and product labelling as being key material issues that are likely to affect the companies' financial performance.[5] It is hard to quantify the risk associated with healthcare litigation. Unresolved litigation may impact a company's valuation; however, it is not until the disputes are resolved and the final settlement amount is confirmed that the real effect on the company can be seen. We engaged with all companies approached for engagement except for Merck & Co. who did not respond. Our engagement discussions targeted a better understanding of four main areas:

- Governance of product quality and safety
- Operational product safety and quality processes
- Litigation risk management
- Off label use and marketing risk

This engagement programme was aimed at collating information, with the primary intended outcome to improve our understanding of how investee companies are managing and mitigating these risks. We also wanted to use the information gathered from these engagements to form an assessment of what best practice looks like.

AstraZeneca GSK MERCK[6] Pfizer PHILIPS

2 About Us | CPSC.gov
3 Johnson & Johnson ordered to pay $4.7bn over talc cancer claims | Retail industry | The Guardian
4 GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data | OPA | Department of Justice
5 This key material issues are derived from the Sustainability Accounting Standards Board (SASB) is a non-profit organisation that has developed sustainability accounting standards. SASB has developed a Materiality Map, which identifies material sustainability factors on an industry-by-industry basis which are most likely to impact a company's financial prospects.
6 Merck & Co. did not respond to our request to engage.

Key findings from our engagements:

- **Governance structures have evolved in reaction to historic controversies**: we have seen some examples of the evolution of governance structures based on previous failures and this often involves improving board and executive visibility of operational activities. Pfizer was fined £1.4bn in 2009[7], one of the largest healthcare fraud settlement and criminal fines charged by US regulators. The company pleaded guilty to charges of advertising the now withdrawn painkiller Bextra for off label purposes (i.e. those not approved by the US Food and Drug Administration). This event led to several changes to the governance and risk oversight processes, including the creation of the Regulatory and Compliance Committee which is now integral to the company's product safety process and links board oversight to commercial developments. Separately, the fall-out from the product recall of certain respiratory devices at Royal Philips has have a significant impact on the leadership, reputation and share price of the company. The company identified governance and management failures related to a lack of accountability in devolved departments and opaque reporting lines. There is a long way to go but the company begun by strengthening the Patient Safety Board Committee that engages with customer feedback – which in turn reports to the board.
- **Those best able to articulate strong quality management are often better product safety performers**: communication is key, and we found that the companies with more recent controversies, including product recalls, often presented an opaquer chain of command and governance structure. High performing companies were able to articulate how the data captured throughout the quality management process influenced board and executive decision making (often mediated by a product quality or regulatory and compliance committee). By it's own admission, Royal Philips had identified opaque reporting lines and devolved departments as a route cause of recent quality management problems. Based on our conversation, it was not clear how the company's governance structure was being streamlined and the issue of independent department structures (and previous issues with product design) would be brought under a tighter governance structure.
- **Companies rarely disclose litigation risk strategies**: despite our interest in understanding how companies generally measure and approach potential litigation risk, little information was provided. Common refrains included following standards risk and compliance procedures and implementation of a culture of compliance & strong business ethics. The exception to this was AstraZeneca who was far more transparent in sharing its general principles on litigation strategy. This openness may be encouraged by the company's lack of major litigation events in recent years. The company had several teams assessing litigation risk at the very beginning of the product development cycle. For both emerging/potential patent infringement and adverse incident events, a litigation strategy is formed as soon as possible. This includes an evaluation of the outcomes of winning or not winning a case. All strategies are validated and monitored by the audit committee of the board. The company will only set aside financial reserves when there is a growing probability of an adverse outcome, and this will be done 12-18 months ahead of any potential action. AstraZeneca does not set aside an ongoing strategic reserve for negative outcomes. This level of transparency provided a welcome and unique view of general approach to litigation risk.
- **Efforts to manage marketing & off label use risk are focused on improving company culture**: Marketing and off label use incidents have led to some of the largest fines in the history of corporate litigation, including Pfizer's 2009 fine referenced above. Following adverse events, we have seen companies extend quality management systems to commercial and marketing departments. Many companies highlight the efforts to implement an ethical culture as the best way to mitigate this risk. Annual attestations to a 'Code of Ethics' was a common practice – with an emphasis on accountability and 'doing the right thing'. The best preventative measure is a culture of speaking up and whistleblowing procedures are an effective way of catching any infringement. The tangible performance of these factors (outside of occurrence of adverse incidents) is difficult to assess. Most companies speak to a positive ethical corporate culture, but this is difficult to measure.

7 Exchange rate from $2.3bn. Conversion factor (USD/GBP 1.6148) as of 31/12/2009. Taken from Bank of England exchange rate database.

Summary

Litigation risk is a structural element of the pharmaceutical and healthcare industries. As highlighted above we found that most companies engaged were not open to discussing litigation strategies and processes. Nearly all companies at the time of engagement were facing current ongoing litigation which may have contributed to the unwillingness to provide detail. This was a limiting factor in our conversations, and it was difficult to improve our understanding of how companies are managing these risks on a systematic basis. There was a geographical distinction to the degree of openness with European companies more willing to outline some elements of strategy. AstraZeneca was notable in this regard.

All companies highlighted the role that company culture plays in good product safety outcomes. The tone set from the top is essential in nurturing an effective company culture on product safety. A key component of this culture is whistleblowing and the ability to voice concerns when risks develop. It is difficult to discern how employee surveys relating to company behaviour but regular monitoring of employee responses demonstrating an ability to voice concerns may be a useful indicator.

The best performing companies demonstrated clear global quality management systems with obvious tiers of escalation from the systems/teams monitoring product performance to the board and executive function. These teams often had a focus on sophisticated data management through the product journey from clinical trials to post-approval performance. These systems allow close to real-time monitoring of the product life cycle, including how long shipments have been sat on the runway during the airfreighting process. Well-functioning systems such as this allow intervention on a proactive basis if the risk of an adverse incident (and potential recall) has been identified. Some companies that had suffered from product recall incidents, such as Royal Phillips, were less able to clearly articulate routes of escalation from specific departments to the board or executive level.

Our main aim from the conversations was to benchmark these companies and establish what good product safety and litigation risk management looks like. This is an important platform for future discussions on the topics and we will continue monitor company progress against best practice expectations.

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