ESG Viewpoint

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Breaking Bad: Business ethics in the pharmaceutical sector

- **Sector:** Pharmaceuticals
- **Issue:** Business conduct
- **Engagement since:** 2008
- **Goal:** Comprehensive overhauling of policies and management systems to mitigate risk of employee misconduct and regulatory breaches as well as reforming corporate culture

- Regulatory violations resulting from corrupt employee conduct has emerged as a key concern in the pharmaceutical industry alongside product quality and safety
- Ever increasing fines and settlements, alongside the cost of remedial actions, undermine profitability and harms companies' societal license to operate
- BMO has engaged extensively on this issue and seen improvements in management programmes and systems; but true reform of corporate culture is only just starting

Key risks

The value of investments and any income derived from them can go down as well as up as a result of market or currency movements and investors may not get back the original amount invested.

Screening out sectors or companies may result in less diversification and hence more volatility in investment values.

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Business ethics breaches have emerged as the most material ESG concern for investors in the pharmaceutical and broader healthcare sector, and has been the key focus of our engagement with the sector in recent years. The industry has been repeatedly become embroiled in allegations with regards to marketing and sales related fraud and other lapses in compliance. Companies have been hampered by substantial risks and mounting costs associated with the prosecution by authorities. We estimate that $50 billion have been paid out by leading pharmaceutical companies in the past decade in conduct related regulatory, settlements fines and costs.

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The US Department of Justice (DoJ) has led the charge against the sector and they have become particularly emboldened post the 2008 global financial crisis to pursue ever larger settlements. Alongside the increased financial penalties, we have been concerned by the reputational damage and operational impact arising from stricter scrutiny of companies and enforcement of regulation in the US, UK and Europe. Key trends we see are "extraterritorial" legislation, meaning that companies may be prosecuted in countries other than their home jurisdiction, as well as strong enforcement actions on companies that fail to prevent corrupt practices through adequate measures[1]. Issues leading to regulatory action include:

- Minimising side-effects
- Off-label promotion
- Price manipulation
- Bribery, kick-backs and other inducements
- Anti-competitive behaviour
- Healthcare system fraud such as false claims

Many of the leading global pharmaceutical companies have fallen foul of these violations. These include **GlaxoSmithKline (GSK)**, **Johnson & Johnson**, **Pfizer** and **Novartis** amongst others. Neither have these breaches been confined to the major developed markets. We have seen a rapid shift in regulatory intolerance to corrupt practices in emerging markets where there had been a perception that rule of law was weak and paying bribes was a cost of doing business. This has been most notable in China, as President Xi Jinping has overseen a widescale crackdown on graft. GSK was fined $490 million after it was found guilty of bribery in 2014[2].

Materiality assessment

The focus on the financial impact has largely been on the immediate cost of dealing with the violations – namely the headline amount of the regulatory settlement. However, we consider this amount to be only a portion of the overall commercial harm that a company suffers when its employees are caught 'breaking bad'. We have identified the following areas which on their own may not be significant but in total can be material to the company's performance. Much of this is also relevant to the financial industry which has struggled with similar issues.

- **Regulatory fine or settlement**: this is often the headline figure that receives the most publicity in the public domain. However, this only amounts to a portion of the total cost incurred over time to resolve breaches. The size of these settlements has become larger – into the billions of dollars and euros – in recent years.
- **Litigation costs and legal provisions**: aside from the legal costs of dealing with specific violations, companies set aside reserves to deal with other regulatory penalties or litigation or damages that are expected to be paid out in the future for similar violations in other jurisdictions.
- **Independent compliance monitor**: the DoJ instructs an independent compliance monitor to be established as part of any deal following a regulatory action. This can be an integral part of any deferred prosecution agreement that has been agreed between DoJ and the company. This involves the DoJ selecting and placing a senior regulatory expert within the company to assess whether the company is living up to commitments it has made. They are free to hire what resources they need to do their job including additional compliance experts and external consultants – this can amount to hundreds of people in the case of large violations. All of this must be paid for by the company during the duration of the monitor. The resulting cost can run to tens, if not hundreds, of millions of dollars per year.
- **Strengthening compliance, internal controls, and audit programmes**: the most obvious increase in ongoing cost is in this area and it has been a major area of new recruitment for companies.
- **Board and senior management effort**: ensuring a successful navigation of the period of the deferred prosecution agreement and meeting the monitor's expectation of reform takes board and senior management time. This is an opportunity cost as management's effort and

[1] For example the US Foreign Corrupt Practices Act and the UK Bribery Act
[2] Full analysis of the GSK's China incident is available in ESG Viewpoint "Bribery in China: Lessons from GSK" February 2014

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time could otherwise be spent delivering on the strategy and growing the business.

- **Longer-term damage to commercial model**: this is the cost to the business arising from damage to reputation, brand and societal license to operate. Major controversies can undermine products and commercial models which may have been reliant on business practices which are regulated out of use.

Engagement action

Sales practices in the pharmaceutical sector have been an area of long-term concern to us and we have been conducting engagement on this issue for more than a decade, both one-on-one and collaboratively in the US with investor groups led by the United Auto Workers. Our engagement intensified as the regulatory fines and settlements mounted and the poor business conduct within the industry became increasingly material to investors. A key turning point was GSK incurring in quick succession a US$3 billion settlement in the US in 2012 for bribing doctors, and the China incident in 2013/14.

Since the start of 2014, we have engaged more than 70 global healthcare companies on this issue including many of the world's leading research and generic pharmaceutical companies. We have travelled to the US, Europe, Japan and China to meet companies and the key recommendations we have been making to businesses are:

- **Clear oversight and accountability from senior executives and the board**: a strong tone from the top that there is zero tolerance of corrupt business practices is essential. There should be clear lines of authority at the board level with regular reporting via the Chief Compliance Officer, and consideration of establishing a board-level committee dedicated to compliance and business ethics risks.
- **Corporate culture reform**: as well as the top-level messaging on cultural reform, we recommend that companies track whether this is translating into change. We have been asking companies to measure and track culture change, and to disclose the results to assure investors, employees and other stakeholders that culture is reforming. Metrics can include more granular whistleblowing usage data (with geographic and business division breakdowns), and aggregated results of staff surveys/training on regulatory compliance.
- **Robust policies and sufficiently resourced management systems**: revising Codes of Conduct, establishing responsible sales and marketing policies, improving risk assessment processes, and strengthening internal controls should be a matter of course. Companies should clarify whether they are backing a single global standard or are taking a market-by-market approach. The former option is more ambitious but more challenging to implement, while the latter is more susceptible to "regulatory arbitrage" by companies which exploit the weak or non-existent rules in many countries.
- **Linking business conduct and regulatory breaches with pay**: targets driven purely by an individual's sales record can incentivise employees to break rules to meet targets and get a larger pay-out. Companies such as GSK have phased these out, replacing them with a wider range of metrics including qualitative ones such as customer satisfaction. Companies should also have a clawback policy ¬which allows for recovery of bonus and other incentive compensation paid to executives and employees found to be involved in misconduct causing financial or reputational harm to the company (see 'Accountability in pay').

Since the start of 2014, we have engaged more than 70 global healthcare companies.

Risk assessment

Over the years, we have occasionally encountered somewhat cynical views that ethics issues are purely a cost of doing business. We do not subscribe to this view. Our analysis has been that there are some companies which have repeatedly attracted litigations, regulatory investigations and settlements, while there are others – with robust practices – which have not attracted any. For example, according to research in the 2016 Access to Medicine Index, only **Gilead** and **Novo Nordisk** (of 20 major global pharmaceutical companies in the rankings) avoided settlements for breaches of criminal or civil laws or regulations relating to corruption or unethical marketing between 2013-2016 (inclusive).

So, how can investors identify companies which are at higher or lower risk of potential violations? Our engagement has allowed us to narrow down to three risk factors.

1. **Countries of operation**: does the company operate in markets which are likely to result in high penalties for regulatory breaches (the US) or in markets where the regulatory quality and rule of law are weak?
2. **How staff are paid**: does the company rely on revenue growth from aggressively growing sales and/or are sales teams incentivised with big bonuses for hitting ambitious (but unrealistic) sales targets? Is the key performance measure for sales teams solely revenue based or does it include other factors such as quality of sales, customer satisfaction and regulatory knowledge?
3. **Drugs portfolio strength**: does this company have a drugs portfolio in a strong competitive position? Would sales staff possibly need to induce doctors in other ways than just the efficacy of the drugs themselves?

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Accountability in pay

Clawback is defined as the provision by which companies can recover bonuses (and other variable pay) after they have vested and have been paid out. These provisions have become increasingly commonplace in certain industries such as banks and pharmaceuticals, and in markets such the US, UK, Switzerland and France. They traditionally cover material financial restatements but there are now increasing moves for clawbacks to also cover instances where employees are held accountable for a broad range of misconduct. We consider clawbacks as an essential and effective way for employers to both incentivize certain behaviours and to hold employees accountable for their actions.

Given the severe financial penalties which can result from staff misconduct, there is growing recognition that effective compensation policies can deter unethical behaviour. In light of this, a working group comprised of **Amgen**, **Bristol-Myers Squibb Company**, **Eli Lilly**, **Johnson & Johnson**, **Merck & Co.**, **Pfizer,** and thirteen institutional investors (including BMO Global Asset Management), endorsed a set of principles called the 'Principal Elements of a Leading Recoupment Policy' (April 2013) aimed at deterring ethical breaches[3].

In 2016, we conducted an engagement project in which we urged 30 leading pharmaceutical companies to establish:

1. **A compensation clawback policy** ¬which would allow for recovery of bonus and other incentive compensation paid to executives and any employee who is involved in misconduct causing financial or reputational harm to the company. We provided a suggested model clawback policy[4].
2. **Clear disclosures and regular reporting of clawback policy implementation** which would allow investors and other interested stakeholders to assess whether the clawback policy has been put to use. This should include details of whether the clawback was used in the reporting period, the nature of the incident which prompted it andhat monetary value was clawed back.

While many companies were willing to implement a Clawback policy covering misconduct, very few were willing to commit to ongoing annual disclosures of whether clawbacks were used in the reporting period. **Shire** was one of the few to do so. We also conducted engagement on the same issue with major financial companies. It is worth noting that **JPMorganChase** have now agreed to do so, and clawback reporting is available in its annual proxy statement.

Verdict

Over the past five years, we have seen a widespread recognition from the pharmaceutical industry that conduct of employees poses a serious risk to commercial performance. We have seen efforts by the companies to improve senior executive and board-level oversight and accountability on this issue, and to; revise and strengthen management systems to assess, identify and monitor potential conduct-related regulatory breaches. Many of the companies are open and willing to discuss the issue and the challenge of reform in an honest fashion. We have had good access to senior executives and board members for in-depth discussions. This has provided signal of how seriously companies are taking reform.

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What we are still not seeing sufficiently is companies clearly linking these issues to pay outcomes in a transparent fashion, nor are we seeing meaningful performance reporting in this area. On the latter point, US companies in particular have been reluctant to disclose how they are performing in this area.

Finally, despite the fact that companies are taking the issue seriously, we need to be realistic in recognising that genuine culture change takes time, particularly for the large multinational firms. Top-level messages being heard and followed by employees in distant markets is one of the key hurdles in implementing long-term change, with the loyalty of employees in many markets often likely to be with their line manager than a Chief Executive in another continent. The time in the industry is for companies not to just say that culture reform is taking place but to show investors the hard evidence that it really is happening.

[3] http://www.uawtrust.org/AdminCenter/Library.Files/Media/501/In%20the%20News/UAW%20RMBT%20-%20Recoupment%20Press%20Release%20-April%204%20 2013%20830%20AM%20_FINAL.pdf
[4] For clients of the ***reo*** engagement overlay service this is provided as a confidential appendix to this ESG Viewpoint

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